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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Enforcement Committee and Work Group on E-Pedigree

Bill Powers, Board President and Chair
Ruth Conroy, PharmD, Board Member
Robert Swart, PharmD, Board Member
Stan Goldenberg, RPh, Board Member

Including Report of the Meeting of September 28, 2006

1. DEA Proposes 90-Day Rule for Prescriptions for Schedule II Controlled Substances

Recommendation: Submit a Statement in Support of the DEA's Proposed Rule to Allow Prescribers to Write Schedule II Controlled Substances for a 90-Day Supply

In California, pharmacy law provides that prescriptions for Schedule II controlled substances are valid for six months. Specifically:

> **11166.** No person shall fill a prescription for a controlled substance after six months has elapsed from the date written on the prescription by the prescriber. No person shall knowingly fill a mutilated or forged or altered prescription for a controlled substance except for the addition of the address of the person for whom the controlled substance is prescribed as provided by paragraph (3) of subdivision (b) of Section 11164.

Federal and state law prohibits refilling a Schedule II prescription; instead requiring a separate, original prescription for what would otherwise be a refill order (same drug, same instructions, same quality). Many prescriptions are written for a 30-day supply, essentially to match requirements of insurance policies that provide a prescription drug benefit.

As a result, for patients on long-term therapy involving Schedule II drugs, the patient must obtain separate prescriptions, written each month for ongoing therapy. This often requires monthly visits with the prescriber simply to obtain the prescription.

The DEA recently released a proposed rule to allow prescribers to prescribe up to a 90-day supply of Schedule II controlled substances during a single office visit. This would allow prescribers to provide patients with three 30-day prescriptions at

once, writing "do not fill" until a specified date on the additional prescriptions so that patients do not have to return simply to obtain a new prescription.

According to the DEA, the proposed rule "will make it easier for patients to obtain their needed medications for conditions such as chronic pain or ADHD, and will ensure that physicians 'have the latitude to prescribe in a manner consistent with their sound medical judgment, while enabling DEA to fulfill its legal obligation to prevent drug abuse and diversion'."

This proposal conforms to longstanding board policy to allow a prescriber to write multiple prescriptions for Schedule II drugs, with a "do not fill before" date entered on the additional prescriptions. However, federal interpretation of the federal law prohibited this practice – unless this regulation is put into effect.

Background material is provided in **Attachment 1**.

This matter was not discussed at the Enforcement Committee, and a motion is required if the board wishes to provide comments in support of this proposed regulation. Comments are due November 6.

2. Combat Methamphetamine Epidemic Act of 2005 Implementation

On September 30, 2006, the second phase of the "Combat Methamphetamine Epidemic Act of 2005" took effect. This act sets conditions and limits for the sale of over-the-counter pseudoephedrine, ephedrine and phenylpropanolamine products, and establishes a new category of scheduled products. These products are subject to sales restrictions, storage requirements and record keeping requirements.

Among the requirements are:

- An individual may purchase no more than 3.6 g of pseudoephedrine in one day
- An individual may purchase no more than 7.5 g of pseudoephedrine in any 30-day period
- The purchaser must present a state or federal government issued photo ID at the time of purchase
- A written or electronic logbook containing all sales transactions must be kept for at least two years from date of purchase
- For each sale, the name and address of the purchaser, product name, quantity, and date and time must be entered into the logbook.
- Products packaged for individual sale containing less than 60 mg of pseudoephedrine are exempt from the logging requirement, but the product must be kept behind the counter.
- The pharmacy must confirm that the information provided by buyer matches that provided on the ID card.
- The buyer must provide a signature verifying the information provided is correct.

Each pharmacy needs to submit to the US Attorney General's Office a self-certification that all individuals who sell such products have undergone the required training. The self-certification is done online, and goes directly to the US Attorney General's Office.

Additional materials prepared by the DEA are in **Attachment 2**.

3. Formulary of Drugs Under Development by the Bureau of Naturopathic Medicine for Naturopathic Doctors

At the September 28, 2006, Enforcement Committee Meeting, Gloria St. John, Executive Director of the California Naturopathic Doctors Association, provided information about California's regulation of naturopathic doctors, a relatively new licensing program enacted by SB 903 (Burton) in 2003.

Ms. St. John was invited to present information at this meeting; however, she is unable to attend. Instead, Carl Hangee-Bauer will provide information about naturopathic doctors and the development of a California formulary for naturopathic doctors.

Background:
Today there are about 200 naturopathic doctors licensed in California by the Bureau of Naturopathic Medicine, a bureau in the Department of Consumer Affairs. Naturopathic doctors must earn 60 hours of continuing education to renew their licenses every two years, of which at least 20 hours must be in pharmacotherapeutics. According California Naturopathic Doctors Association, naturopathic medicine is a form of primary care that is an art, science, philosophy and practice involving diagnosis, treatment and prevention of illness.

Naturopathic doctors are allowed by California law to prescribe hormone and epinephrine for anaphylaxis independently and to prescribe Schedule III through IV drugs under protocol with an MD. To furnish and order drugs, NDs must obtain a furnishing number from the bureau, which requires completion of a 48-hour course in pharmacology.

Naturopathic doctors can administer, order and prescribe food, extracts of food, nutraceuticals, vitamins, amino acids, minerals, enzymes, botanicals and their extracts, botanical medicines, homeopathic medicines, all dietary supplements and non prescription drugs, consistent with the following routes of administration: oral, nasal auricular, ocular, rectal, vaginal, transdermal, intradermal, subcutaneous, intravenous, and intramuscular. The bureau states that NDs may use ocular and intravenous routes of administration only if they are clinically competent to do so.

Senate Bill 907 specified that the Bureau of Naturopathic Medicine establish a Naturopathic Formulary Committee to determine the formulary from which

naturopathic doctors will prescribe. The committee is comprised of an equal number of physicians, pharmacists, and naturopathic doctors. The committee is to make recommendations regarding the prescribing, ordering and furnishing authority of an ND and the required supervision and protocols for these functions. The formulary is to be submitted to the Legislature by January 1, 2007 regarding the prescribing and furnishing authority of an ND, and the required supervision and protocols for the use of IV and ocular routes of prescription drug administration.

Currently 13 states license NDs, and nine of these states allow NDs to prescribe independently with no MD oversight. No state reports disciplining NDs for prescribing. The Naturopathic Formulary Committee concluded that there are only a limited number of MDs who possess the training and philosophy needed to supervise NDs. Moreover, the few MDs who do qualify have difficulty obtaining adequate malpractice coverage. Based upon these factors, the committee believes that MD supervision of NDs is untenable.

The Naturopathic Formulary Committee recommends:

- Inclusion Formulary: Pursue changes to California law to allow NDs to be able to independently prescribe without MD supervision from the committee-recommended formulary.
- IV Therapy: NDs should be able to practice without MD supervision after completing specific CE comprised of a 25-hour course, with 14 hours of practicum, and a refresher course every five years. Upon completion, NDs will be able to independently administer drugs listed in the IV formulary via the IV route.
- Chelation Therapy: Any ND who performs this therapy (used to detoxify for heavy metal exposures) must complete a 12-hour CE course in addition to the IV therapy course.

Attachment 3 contains the draft formulary developed by the Naturopathic Formulary Committee. Addition background information about naturopathic doctors is also included, as are the formularies used by naturopathic doctors in Oregon and Arizona.

5. Plan B Emergency Contraception Becomes Over-the-Counter for Patients 18 and Older

Recommendation: Refine questions and answers on emergency contraception available from pharmacies and place online

In mid-August, the FDA reclassified Plan B from prescription status to over-the counter (OTC) status for emergency contraception for patients aged 18 and older. For patients 18 years and younger, Plan B remains a prescription drug.

In California existing law contains provisions that allow a specially qualified pharmacist to prescribe and dispense emergency contraception, using a variety of

drugs, including Plan B (California Business and Professions Code section 4052, and California Code of Regulations section 1746 – see **Attachment 4**).

Although OTC, Plan B may be sold only by pharmacies and must be kept behind the pharmacy counter. Anyone, a pharmacist, pharmacist intern, pharmacy technician or clerk may sell the drug. Individuals who are 18 and order may purchase the drug. No records of these sales are required.

If the patient purchasing Plan B is less than18, then the pharmacist, if qualified, may write a prescription for Plan B or any other medication authorized in the state protocol for emergency contraception or in the protocol established with a physician. In this case, the emergency contraception drug is a prescription drug, and all requirements for dispensing prescription drugs apply, including consultation by the pharmacist.

Also, other drugs listed in the state protocol for emergency contraception remain prescription drugs, not over-the-counter, regardless of the age of the patient or purchaser.

In response to questions asked of the board initially upon the FDA's reclassification, staff developed draft questions and answers **Attachment 5**. During the Enforcement Committee Meeting, these Qs and As were slightly modified to those provided in this packet.

Once approved by the board, the material will be added to the board's Web site.

Additional materials about the reclassification of Plan B to OTC status are also provided in **Attachment 4.**

6. Report of the Work Group on E-Pedigree

At the September Meeting, Supervising Inspector Nurse provided a Power Point presentation on changes to California's e-pedigree requirements that were amended into SB 1476, which was signed by the Governor two days after the Enforcement Committee meeting. A copy of this Dr. Nurse's Power Point presentation is provided as **Attachment 6,** and provides a good overview of components enacted in SB 1476.

Senate Bill 1476 delays implementation of e-pedigree requirements in California until 2009, with the board having the ability to delay implementation until January 1, 2011.

The board drafted additional amendments into SB 1476 that would clarify that the e-pedigree system must interoperable through all levels in the distribution system, that serialization is needed to product container level, that the board must be

notified if counterfeit drugs or fraudulent pedigrees are suspected, that drugs returned to a wholesaler must maintain the same pedigree, that repackagers must maintain the pedigree into repackaged items, and that drug samples do not require pedigrees.

The board will need to develop regulations to specify some components enacted in SB 1476. This includes the process for notifying the board about counterfeit drugs, and what license number must be entered into the pedigree.

Acting Chairperson Goldenberg emphasized at the meeting that the e-pedigree work group meetings over the next few years will be crucial to being able to develop necessary regulations and move forward timely with implementation of these requirements that are necessary to ensure a safe distribution system for patients.

EPCglobal provided a PowerPoint Presentation about industry's progress in developing unified standards for electronic pedigrees **Attachment 7**. There continues to be progress in development, and testing on a "last call working draft" version of a standard is underway. The purpose of this standard is to ensure that different entities in the supply chain can all access the pedigree and interpret it in the same manner.

Among the issues to be resolved include decommissioning of a chip to protect patient privacy, item level tagging – e.g., whether high frequency or ultrahigh frequency would be best. It may the third quarter of 2007 before the standard for item tagging is ready.

EPCglobal reported on a pilot study conducted; recently six companies were given seven of the most challenging scenarios and test data to create pedigrees against. A total of 42 pedigrees were tested. Their pedigrees were compared, line-by-line, with the expected outcome from the standard. There were no changes from the standard.

McKesson provided a brief overview of the "On Track" pilot program underway among various entities in the supply chain regarding e-pedigree issues such as data sharing, track and trace visibility, tag data components, tag frequency and reading ranges, and changes needed in current business processes **Attachment 8**. Generation 1 will be completed in December 2006, when a generation 2 study will begin.

Johnson and Johnson stated that they are working to implement the e-pedigree requirements but they believe implementation is still 4-5 years away. The infrastructure is not ready, and that not all products really need electronic pedigrees.

During 2006-08, Johnson and Johnson will be working on building the structure to use e-pedigrees, and test 3-5 products using both RFID and 2-D bar code technology.

In 2010, the standards will be deployed, and they believe that 50 percent of their products will be tagged by 2011. But Johnson and Johnson believes that implementation cannot be fully achieved until 2011-2012.

The company emphasized the importance of interoperability – of one standard used by everyone, and indicated that regulations to require a specific standard may be required.

The California Retailers Association stated that one standard is needed because pharmacies are at the end of the process and cannot function with multiple electronic pedigree systems, each requiring unique equipment. At this stage, the CRA cannot offer a timeline for implementation because they are waiting for the drug manufacturers and wholesalers to refine the standards. The CRA also emphasized that they are participating in the On Track and EPCglobal standards setting and pilot tests of electronic pedigrees.

Presentation by Gene Alley, Stat Pharmaceuticals

Stat Pharmaceuticals provided information about its operations as a secondary wholesaler, and the association of secondary wholesalers the company is part of, which is not a part of the EPCglobal group. Gene Alley stated the difficulty that the FDA's authorized distributor and paper pedigree standards that will go into effect in December 2006 will have on such companies as his. He added that by exempting authorized distributors from pedigree requirements but requiring secondary wholesalers to obtain pedigrees from the authorized wholesalers, especially since the authorized distributors will not provide pedigrees, will force companies such as his out of business. Stat Pharmacecuticals reports that it plans to initiate litigation to challenge the FDA's rule, on the theory that it excludes secondary wholesalers from the marketplace.

Chairperson Goldenberg asked Mr. Alley to come to the October Board Meeting to provide a presentation. Materials provided by Mr. Alley are in **Attachment 9.**

Mr. Alley provided the following summary statement to me:

> STAT Pharmaceuticals of San Diego and the National Coalition of Pharmaceutical Distributors (NCPD) support California's pedigree laws that require ALL stakeholders to play by the same rules, with NO exemptions for the "Authorized Distributors". I will urge you at your 10/25 meeting to not yield to the special interest groups that will try to get California to provide them with a Florida like exemption so they don't have to pass pedigrees. I have attached enough information along with the content of this letter to inform the board as to why the board MUST keep the CA law the way it

is. FYI, several of the letters contain the same information along with their unique contents.

Note: effective December 2, 2006, the FDA's requirements for drug pedigrees go into effect, after years of delay following enactment of the Prescription Drug Marketing Act in 1988. These requirements require a paper pedigree for drugs that are distributed outside the "authorized" distribution channel (from manufacturer, to specific (authorized) wholesaler, to pharmacy). This is a very limited pedigree. So secondary wholesalers, such as Stat, must obtain and pass paper pedigrees to their purchasers. California's law, which is set to take effect in January 2009, is much stronger and requires electronic pedigrees for all drugs through the distribution channel identifying every change in ownership from the manufacturer to the pharmacy.

The federal rule will take effect nationwide on December 2. In recognition of the problem to pharmacies that may not always be certain who is an authorized distributor, the board added the following into SB 1476:

> 4163.1. It is the intent of the Legislature that commencing on January 1, 2007, and continuing through the full implementation of the pedigree requirements specified by Section 4163, manufacturers and wholesalers shall use best efforts to provide in the most readily accessible form possible, information regarding the manufacturer's specific relationships in the distribution of dangerous drugs with wholesalers.

7. Meeting Summary

A summary of the September 28, 2006 Enforcement Committee and Workgroup on E-Pedigree is provided as **Attachment 10**.

8. Report on Enforcement Actions

A report of enforcement actions taken since July 1, 2006 is provided as **Attachment 11**.

Attachment 1

DEA Proposes 90-Day Prescriptions for Schedule II Controlled Drugs

- Click here to view ASHP Press Releases Archive
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DEA Proposes 90-Day Prescriptions for Schedule II Controlled Substances

BETHESDA, MD, 08 September 2006 — The Drug Enforcement Administration (DEA) this week proposed a rule to allow physicians, when medically appropriate, to prescribe up to a 90-day supply of Schedule II controlled substances during a single office visit.

The law prohibits Schedule II controlled substance prescriptions to be refilled. If a prescriber wants a patient to continue on the same Schedule II controlled substance beyond the amount specified on the first prescription, the prescriber must provide a separate prescription.

To get around the law, prescribers often provide patients with at least three 30-day prescriptions for Schedule II substances at once, writing "do not fill" until a specified date on the additional prescriptions so that patients do not have to return to their health care provider's office each month for a new prescription, according to DEA.

During a media briefing Wednesday, DEA chief Karen Tandy said the agency's regulations that implement the law did not address the issuance of multiple prescriptions.

According to the agency, some prescribers mistakenly interpreted a 2004 DEA interim policy statement as requiring patients to visit their providers each month to obtain a prescription for a Schedule II substance.

DEA issued a clarification document in 2005, which asserted that the 2004 document "did not state that such patients must visit their physician's office every month to pick up a new prescription."

The 2005 clarification document "explained some of the possible ways in which, under appropriate circumstances, patients can continue to receive Schedule II prescriptions without visiting their physicians' offices every month," officials said.

Tandy said that her agency heard from hundreds of health professionals and the public about the burden placed on patients to visit a physician's office each month to get a new prescription for an already diagnosed chronic condition, such as attention-deficit/hyperactivity disorder (ADHD) or chronic pain.

Officials said that the newly proposed rule, which was published in Wednesday's *Federal Register*, will make it easier for patients to obtain their needed medications for conditions such as chronic pain or ADHD, and will ensure that physicians "have the latitude to prescribe in a manner consistent with their sound medical judgment, while enabling DEA to fulfill its legal obligation to prevent drug abuse and diversion."

According to the agency, Schedule II controlled substances have the highest potential for abuse and are the most likely to cause dependence of all the controlled substances with FDA-approved labeling.

"Physicians must, therefore, employ the utmost care in determining whether their patients for whom they are prescribing Schedule II controlled substances should be seen in person each time a prescription is issued or whether seeing the patient in person at somewhat less frequent intervals is consistent with sound medical practice and appropriate safeguards against diversion and misuse," DEA stated in Wednesday's *Federal Register* notice.

The proposed rule is open for public comment until November 6.

DEA also issued a new policy statement on Wednesday which outlines the longstanding legal requirements on dispensing controlled substances for the treatment of pain.

The document specifies DEA's policy for taking appropriate legal action "against those very few physicians who illegally prescribe controlled substances."

"The DEA has an obligation under the law and to the public to ensure that controlled substances are prescribed and dispensed only for legitimate medical purposes in accordance with the Controlled Substances Act," said William Jacobs, cofounder and president of NexStep Integrated Pain Care, a Florida-based group of pain treatment experts.

"The release of the DEA's policy statement today reemphasizes the administration's commitment to fulfill those obligations while leaving medical decision making in the hands of medical practitioners," he told reporters.

In addition, the agency launched a new Web site at www.deadiversion.usdoj.gov/crim_admin_actions/index.html that lists facts about criminal cases against physicians involved in diversion of controlled substances.

The Web site is intended to help dispel rumors that DEA targets physicians who prescribe pain medication, officials said.

"I urge all physicians to learn the facts about how and why the DEA investigates a doctor on the newly added webpage," Jacobs said. "There is no giant computer counting the number of prescriptions or pills a physician writes and then signaling a SWAT team attack on a physician's office. There has been a significant amount of misinformation propagated about some of the more public cases. In most cases the DEA becomes aware of a doctor selling prescriptions from local pharmacists or physicians."

"Physicians who know the rules and follow them have nothing to fear from the DEA," he declared.

—Donna Young

News Release
FOR IMMEDIATE RELEASE
September 06, 2006

Working Together: DEA and the Medical Community

DEA Issues Policy Statement on Dispensing and Prescribing Controlled Substances for Pain Treatment

Today, DEA is unveiling a proposed rule that will make it easier for patients with chronic pain or other chronic conditions, to avoid multiple trips to a physician. It will allow a physician to prescribe up to a 90-day supply of Schedule II controlled substances during a single office visit, where medically appropriate.

The Notice of Proposed Rulemaking is accompanied by a policy statement, "Dispensing Controlled Substances for the Treatment of Pain," which provides information requested by medical professionals regarding DEA's position on this important issue.

Also new today, DEA is launching a new page on its website (www.dea.gov) called "Cases Against Doctors." Everyone will be able to see for themselves the criminal acts committed by those few physicians who are subject to prosecution or administrative action each year.

DEA's guiding principle is to prevent the abuse and diversion of prescription controlled substances, which have become increasingly popular and deadly, without impacting the ability of patients with legitimate need to have full access to pain relief prescribed by their physician. DEA remains committed to the September 2001 Balanced Policy of promoting pain relief and preventing abuse of pain medications.

"We listened to the comments of more than 600 physicians, pharmacists, nurses, patients, and advocates for pain treatment, and studied their concerns carefully. Today's policy statement is the result of that collaboration. The policy statement reiterates the DEA's commitment to striking the proper balance to ensure that people who need pain relief get it, and those who abuse it, don't," said DEA Administrator Karen P. Tandy.

The new policy statement outlines the longstanding legal requirements on dispensing controlled substances for the treatment of pain. It addresses the requirement that controlled substances be prescribed only for a legitimate medical purpose, examines the issues surrounding the treatment of pain, and elaborates on DEA's policy for taking appropriate legal action against those very few physicians who illegally prescribe controlled substances.

"We believe that the statement and proposed rule will help the medical professional ensure that only patients who need medication for pain relief get it. The statement reflects an awareness of patients' needs as well as the importance of preventing any illegal diversion of prescription drugs," added Administrator Tandy.

The overwhelming majority of medical professionals who provided written input expressed concern about the statutory provision that restricts doctors from refilling schedule II prescriptions. In response, DEA has developed a proposed regulation that clarifies the statute and expressly allows for the issuance of multiple Schedule II prescriptions in appropriate circumstances. This proposed rule, which is being published for public comment as required by law, is intended to make sure patients get the pain relief they need, and that doctors have the latitude to prescribe in a manner consistent with their sound medical judgment, while enabling DEA to fulfill its legal obligation to prevent drug abuse and diversion.

Under the proposed rule, physicians, as they have always done, must determine whether a patient has a legitimate medical need for the prescribed substance, and the physician must be acting in the usual course of professional practice. DEA's proposed regulation would then permit the physician to issue multiple Schedule II prescriptions, during a single office visit, allowing patients to receive a total of up to a 90-day supply of controlled substances according to the fill

date that the doctor gives the pharmacist.

A sixty-day public comment period on the Notice of Proposed Rulemaking begins on September 6, 2006, the date of publication.

To aid doctors in their responsibility to prevent the diversion and abuse of controlled substances, DEA also has updated its Practitioner's Manual, which has been posted on www.dea.gov today.

Prescription drug abuse is a growing epidemic and requires everyone's vigilance. Statistics show that:

- Nearly 1 in 10 high school seniors admits to abusing powerful prescription painkillers.
- Today, more new drug users have begun abusing pain relievers (2.4 million) than marijuana (2.1 million) or cocaine (1.0 million).
- 6 million Americans are currently abusing controlled substance prescription drugs- that is more than the number abusing cocaine, heroin, hallucinogens, and inhalants, combined.
- Researchers from the Centers for Disease Control and Prevention report that opioid prescription painkillers now cause more drug overdose deaths than cocaine and heroin combined.
- Admissions to treatment for prescription opiates swelled by a third in just two years (from 46,972 in 2002 to 63,243 in 2004).

The law charges DEA with responsibility to combat this exploding problem by preventing the diversion of legal drugs into the illegal market where they can be abused. The medical community shares DEA's urgent desire to put an end to this growing and dangerous illegal activity.

"Today's policy statement reaffirms that DEA wants doctors to treat pain as is appropriate under accepted medical community standards. Physicians acting in accordance with accepted medical practice should be confident that they will not be criminally charged for prescribing all appropriate pain medications," Administrator Tandy concluded.

Case Against Doctors>>

Practitioners Manual>>

DEA Policy: Dispensing Controlled Substances for the Treatment of Pain>>

DEA Proposal Notice: Issuance of Multiple Prescriptions for Schedule II Controlled Substances>>

Administrator Tandy's DEA Issues Policy Statement on Dispensing and Prescribing Controlled Substances for Pain Treatment (video clip)>>

Attachment 2

Combat Methamphetamine Epidemic Act of 2005 Implementation

Combat Methamphetamine Epidemic Act of 2005

Alternate Forms of Identification

8 CFR 274a.2(b(1)(v)(A) and 274a.2(b)(1)(v)(B)

[as of September 18, 2006]

The Combat Methamphetamine Epidemic Act of 2005 (Title VII of Pub. L. 109-177) (CMEA) requires on and after September 30, 2006, that an individual must present an identification card that includes a photograph and is issued by a State or the Federal government or a document considered acceptable under 8 CFR 274a.2(b)(1)(v)(A) and (B) when purchasing a scheduled listed chemical product from a regulated seller. The regulated seller must verify that the name on the identification corresponds to the name the purchaser enters in the logbook which CMEA requires the regulated seller to maintain. As of September 18, 2006, alternate forms of identification listed in 8 CFR 274a.2(b)(1)(v)(A) and (B) include the following:

- United States passport (unexpired or expired).
- Alien Registration Receipt Card or Permanent Resident Card, Form I–551.
- An unexpired foreign passport that contains a temporary I–551 stamp.
- An unexpired Employment Authorization Document issued by the Immigration And Naturalization Service which contains a photograph, Form I–766; Form I–688, Form I–688A, or Form I–688B.
- In the case of a nonimmigrant alien authorized to work for a specific employer incident to status, an unexpired foreign passport with an Arrival-Departure Record, Form I–94, bearing the same name as the passport and containing an

endorsement of the alien's nonimmigrant status, so long as the period of endorsement has not yet expired and the proposed employment is not in conflict with any restrictions or limitations identified on the Form I–94.

- For individuals 16 years of age or older:
  - A driver's license or identification card containing a photograph, issued by a State or an outlying possession of the United States. If the driver's license or identification card does not contain a photograph, identifying information shall be included such as: name, date of birth, sex, height, color of eyes, and address.
  - School identification card with a photograph.
  - Voter's registration card.
  - U.S. military card or draft record.
  - Identification card issued by Federal, State, or local government agencies or entities. If the identification card does not contain a photograph, identifying information shall be included such as: name, date of birth, sex, height, color of eyes, and address.
  - Military dependent's identification card.
  - Native American tribal documents.
  - United States Coast Guard Merchant Mariner Card.
  - Driver's license issued by a Canadian government authority.
- For individuals under age 18 who are unable to produce a document from the list above of acceptable documents for persons age 16 years and older:
  - School record or report card.

- Clinic doctor or hospital record.
- Daycare or nursery school record.

The list of acceptable forms of identification, as cited in CMEA, may change ("in effect on or after the date of enactment"). DEA has no discretion to alter the list.

U.S. Department of Justice
Drug Enforcement Administration
Office of Diversion Control

DEA has developed training materials regarding self-certification training for regulated sellers of non-prescription drug products containing ephedrine, pseudoephedrine, and phenylpropanolamine as required by the Combat Methamphetamine Epidemic Act of 2005 (Title VII of Public Law 109-177).

The Act states that "A regulated seller may not sell any scheduled listed chemical product at retail unless the seller has submitted to the Attorney General the self-certification referred to in subparagraph (A)(vii)" (Combat Methamphetamine Epidemic Act § 711(b)(1), 21 U.S.C. § 830(e)(1)(B)(i) as amended). Section 711(b)(1) (21 U.S.C. § 830(e)(1)(A)(vii) states: "In the case of individuals who are responsible for delivering such [scheduled listed chemical] products into the custody of purchasers or who deal directly with purchasers by obtaining payments for the products, the seller has submitted to the Attorney General a self-certification that all such individuals have, in accordance with criteria under subparagraph (B)(ii), undergone training provided by the seller to ensure that the individuals understand the requirements that apply under this subsection and subsection (d) ["FALSE STATEMENTS OR MISREPRESENTATIONS BY PURCHASERS"]".

Two sets of training materials have been developed: one for regulated persons who are mobile retail vendors, and one for regulated persons who are not mobile retail vendors. Regulated sellers must use the content of these training materials in the training of their employees who sell scheduled listed chemical products. A regulated seller may utilize additional content in its training program, but DEA's posted material must be included.

Training Required to Sell Drug Products Containing Ephedrine, Pseudoephedrine, and Phenylpropanolamine

U.S. Department of Justice
Drug Enforcement Administration
Office of Diversion Control

Why do I have to take this training?

- Because a new federal law, the Combat Methamphetamine Epidemic Act of 2005, says you cannot sell Scheduled Listed Chemical Products containing ephedrine, pseudoephedrine, or phenylpropanolamine until you have completed this training.
- This training will help you to understand the laws and what you must know before you can sell these drug products.

What am I going to learn from this training?

This training will teach you:

- that you must keep a logbook of sales;
- that the name on the identification your customer shows you matches the name your customer wrote in the logbook;
- that these Scheduled Listed Chemical Products must be kept either behind the counter or in a locked cabinet;
- that you can sell only a limited amount (3.6 grams) of these drug products to each customer per day;
- that your customer can only buy a limited amount, (9 grams) of these drug products in a 30-day period.

What are ephedrine, pseudoephedrine, and phenylpropanolamine used for?

- Ephedrine and pseudoephedrine are used to make cough, cold and allergy drug products.
- Ephedrine is used to treat breathing problems.
- Pseudoephedrine is used to treat colds, allergies, and runny noses.
- Phenylpropanolamine is only sold by prescription for animal use.

What are methamphetamine and amphetamine?

- Methamphetamine and amphetamine are highly addictive drugs that are dangerous to use and make.
- Other common names for methamphetamine are "meth," "crystal," "crank," and "ice."
- Ephedrine and pseudoephedrine can be used illegally to make methamphetamine.
- Phenylpropanolamine can be used illegally to make amphetamine.

What is the purpose of the new law?

- The new law establishes requirements for selling Scheduled Listed Chemical Products containing ephedrine, pseudoephedrine, and phenylpropanolamine because these ingredients can be used illegally to make methamphetamine or amphetamine.
- In all states every seller of these drug products must follow the new law.
- Some states have tougher laws than the current federal law. If your state has tougher laws, those laws must be followed in addition to the federal law.

What information must be in the logbook?

- You must keep a logbook which contains a written or electronic list of sales of drug products containing ephedrine, pseudoephedrine, and phenylpropanolamine.
- You must write or enter in the logbook the name of the drug product and the quantity sold.
- Your customer must write or enter in the logbook their name and address, and the date and time of the sale.
- Your customer must also sign the logbook (signature).

Identification and Verification

- Your customer must show you a photo identification issued by a State or the federal government. If your customer does not have a photo identification, ask your supervisor for help.
- You cannot sell Scheduled Listed Chemical Products containing ephedrine, pseudoephedrine, or phenylpropanolamine to customers unless they present appropriate identification.
- You must verify that your customer's name on the photo identification matches the name your customer wrote in the logbook.
- You must verify that the date and time of the sale that your customer wrote in the logbook are correct.

When is my customer NOT required to sign the logbook?

- If your customer buys **a single package containing not more than 60 milligrams of pseudoephedrine*** (one 60 mg tablet or two 30 mg tablets)
  - Your customer does not have to sign the logbook.
  - Your customer does not have to show identification.

*** Note: does not apply to ephedrine or phenylpropanolamine**

Who can see the logbook information?

- You must keep the logbook secure.
- You may share information in the logbook:
  - To comply with the law; and
  - For a product recall.
- Logbook information may **only** be shown to local, state and federal law enforcement.
- Information in the logbook may be copied, inspected only, or turned over entirely.
- Ask your supervisor for further information about sharing information.

How do I store these drug products?

- You must store drug products containing ephedrine, pseudoephedrine, and phenylpropanolamine either behind the counter or in a locked cabinet.
- You must give the drug product directly to the customer who signed the logbook.

How much of these drug products can I sell to each customer per day?

- You cannot sell more than **3.6 grams per day to each customer** of Scheduled Listed Chemical Products containing ephedrine, pseudoephedrine or phenylpropanolamine.
- Refer to the charts on the next two slides for the amount of tablets or liquids that equals 3.6 grams.
- No matter how many sales you make to a customer, you cannot legally sell more than 3.6 grams per day of these drug products to the same person.

Number of tablets in 3.6 grams

U.S. Department of Justice
Drug Enforcement Administration
Office of Diversion Control

Ingredients	Number of tablets = 3.6 grams
25 mg Ephedrine HCl	175 Tablets
25 mg Ephedrine Sulfate	186 Tablets
30 mg Pseudoephedrine HCl	146 Tablets
60 mg Pseudoephedrine HCl	73 Tablets
120 mg Pseudoephedrine HCl	36 Tablets
30 mg Pseudoephedrine Sulfate	155 Tablets
60 mg Pseudoephedrine Sulfate	77 Tablets
120 mg Pseudoephedrine Sulfate	38 Tablets
240 mg Pseudoephedrine Sulfate	19 Tablets
Phenylpropanolamine (PPA)	FDA issued a voluntary recall as being unsafe for human consumption. Veterinary use is by prescription only.

Liquids - Number of milliliters in 3.6 grams

Ingredients	Number of milliliters (ml) = 3.6 grams
6.25 mg Ephedrine HCl/ 5 ml Liquid	3515 ml
15 mg Pseudoephedrine HCl / 1.6 ml Liquid	468 ml
7.5 mg Pseudoephedrine HCl / 5 ml Liquid	2929 ml
15 mg Pseudoephedrine HCl / 5 ml Liquid	1464 ml
15 mg Pseudoephedrine HCl / 2.5 ml Liquid	732 ml
30 mg Pseudoephedrine HCl / 5 ml Liquid	732 ml
30 mg Pseudoephedrine HCl / 2.5 ml Liquid	366 ml
60 mg Pseudoephedrine HCl / 5 ml Liquid	366 ml
Phenylpropanolamine	FDA issued a voluntary recall as being unsafe for human consumption. Veterinary use is by prescription only.

How much of these drug products can my customer buy in a 30-day period?

- Your customer cannot buy more than **9 grams in a 30-day period** of Scheduled Listed Chemical Products containing ephedrine, pseudoephedrine, or phenylpropanolamine.

- Refer to the charts on the next two slides for the amount of tablets or liquids that equals 9 grams.

Number of tablets in 9 grams

Ingredient	Number of tablets = 9 grams
25 mg Ephedrine HCl	439 Tablets
25 mg Ephedrine Sulfate	466 Tablets
30 mg Pseudoephedrine HCl	366 Tablets
60 mg Pseudoephedrine HCl	183 Tablets
120 mg Pseudoephedrine HCl	91 Tablets
30 mg Pseudoephedrine Sulfate	389 Tablets
60 mg Pseudoephedrine Sulfate	194 Tablets
120 mg Pseudoephedrine Sulfate	97 Tablets
240 mg Pseudoephedrine Sulfate	48 Tablets
Phenylpropanolamine (PPA)	FDA issued a voluntary recall as being unsafe for human consumption. Veterinary use by prescription only.

Liquids - Number of milliliters in 9 grams

Ingredients	Number of milliliters (ml) = 9 grams
6.25 mg Ephedrine HCl / 5 ml Liquid	8788 ml
15 mg Pseudoephedrine HCl / 1.6 ml Liquid	1171 ml
7.5 mg Pseudoephedrine HCl / 5 ml Liquid	7323 ml
15 mg Pseudoephedrine HCl / 5 ml Liquid	3661 ml
15 mg Pseudoephedrine HCl / 2.5 ml Liquid	1830 ml
30 mg Pseudoephedrine HCl / 5 ml Liquid	1830 ml
30 mg Pseudoephedrine HCl / 2.5 ml Liquid	915 ml
60 mg Pseudoephedrine HCl / 5 ml Liquid	915 ml
Phenylpropanolamine	FDA issued a voluntary recall as being unsafe for human consumption. Veterinary use is by prescription only.

What I have learned from this training?

Now I know:

- how to keep a logbook of sales;
- how to verify information my customer provides me;
- that these drug products must be stored either behind the counter or in a locked cabinet;
- that I cannot sell more than 3.6 grams of these drug products per day to each customer; and
- that my customer cannot buy more than 9 grams of these drug products in a 30-day period.

Additional information

- The Combat Methamphetamine Epidemic Act of 2005 can be found as Title VII of the USA PATRIOT Improvement and Reauthorization Act of 2005 (Public Law 109-177)
- The Combat Methamphetamine Epidemic Act of 2005 was implemented into the Controlled Substances Act: 21 U.S.C. 801-971
- For additional information see http://www.deadiversion.usdoj.gov

Attachment 3

Recommended California Naturopathic Doctors' Drug Formulary and Background Information about Naturopathic Doctors

DRAFT

Findings and Recommendations
Regarding the Prescribing and Furnishing Authority
of a Naturopathic Doctor

Department of Consumer Affairs
Bureau of Naturopathic Medicine
September 17, 2006
(Revised)

Recommendation # 6—Pharmaceutical Formulary.

It is recommended that changes be made to statutory law and subsequently to the Bureau's regulations to allow NDs to be able to independently prescribe, without supervision or protocol, from the formulary below (in addition to what is currently allowed by Section 3640.7). It is recommended that this formulary be included and maintained in the California Code of Regulations, rather than in statute. It is further recommended that a statutory change be made in order to require the Bureau in consultation with the Committee and the Naturopathic Advisory Council to review and update the naturopathic formulary on an annual basis. Changes to the formulary by the Bureau would be recommended by the Committee and approved by the Naturopathic Advisory Council.

* = Available over the counter

ANTIBIOTICS
Amebecides
Antifungal agents
Antihelminthics
Antimalarial preparations (includes artemesin, derived from Artemesia annua)
Antiprotozoal agents
Antiviral agents
Bacitracin
Cephalosporins and related antibiotics
Fluroquinolones
Macrolides
Nitrofurantoins
Metronidazole
Neomycin
Nitrofurans
Penicillins
Quinalones
Sulfonamides
Tetracyclines

PAIN CONTROL AGENTS
Salicylates
NSAIDS
Opioid Analgesic Combinations - Schedules III, IV, and V only

DERMATOLOGICALS
Astringents*
Anti-fungals - topical
Anti-infectives, topical
Anti-inflammatory agents

Anti-psoriatic agents
excluding methotrexate
Antihistamine preparations, topical
Antiseborrheic products
Arnica
Cleansers*
Counterirritants
Destructive agents
Diaper rash products*
Dressings and granules
Drying agents
Eflornithine HCl
Emollients*
Enzyme preparations
Immunomodulators, topical
Irrigating solutions
Keratolytic agents
Local anesthetics
Topical
IM and SQ Procaine and Lidocaine
Minoxidil
Ointment and lotion bases*
Photochemotherapy
Pigment agents
Poison ivy products, topical*
Protectants
Pyrithione zinc
Retinoids — dermatologic (oral)
Rexinoids
Rubs and liniments*
Scabicides/pediculicides
Sunscreens*
Topical combinations, miscellaneous*
Topical steroids
Wound healing agents*

OPHTHALMIC AGENTS
Antibiotics
Mast cell stabilizers
Ophthalmic antihistamines
Otic antibiotics and combination preparations

RESPIRATORY AGENTS
Bronchodilators
Expectorants
Antihistamines

Antitussives and combined antitussives
Bronchodilators
Leukotriene formation inhibitors
Leukotriene receptor antagonists

GASTROINTESTINAL AGENTS
Proton pump inhibitors
Antidiarrheals
Gallstone Solubilizing Agents
H. pylori agents

CARDIOVASCULAR AGENTS
Anti-hyperlipidemic agents

RENAL AND GENITOURINARY AGENTS
Vaginal Preparations

DIAGNOSTIC AGENTS
In vitro Diagnostics Aids
In vivo Diagnostic Biologicals

VACCINES

ANTI-DIABETIC AGENTS

IV FORMULARY

I. Category: Amino Acids and Glutathione

II. Category: Vitamins

III. Category: Minerals

IV. Category: Electrolytes and Diluents

V. Category: Specialty Products
DMSO

VI. Category: Biologicals

Definition:

Biologicals are natural substances and compounds that exist in nature or are formed by natural forces, processes or entities including their constituents, preparations, concentrates, refinements, isolates, extracts, derivatives, byproducts, ligands and metabolites, and the synthetic chemical surrogates, isomers and analogues of these. A natural substance may be the crude substance or a constituent derived from the crude substance, or a synthesized chemical surrogate, isomer or analogue of the constituent.

⇒ Substances:

2. Biotin	2. Inositol	3. Choline
5. Caffeine	5. CoQ-10	21. Glucosamine HCl/Sulfate
22. Glucose	23. Glycyrrhizic Acid	24. Homeopathics
25. Hydrogen Peroxide	26. Hydrochloric Acid	27. Lipoic Acid
28. MSM	29. Nicotinic Acid	30. Phospholipids (Phosphatidyl choline, ethanolamine, inositol)
31. SAMe	32. Silymarin	33. Acetyl-l-carnitine
34. L-Carnitine	[redacted]	

VII. Category: Botanicals

None.

VIII. Category: Chelating Agents:

⇒ Substances:

DMPS	EDTA

IX. Any substance included in Section 3640(c)(1) which is part of an IRB.

NaturoWatch℠

The Skeptical Guide to Naturopathic History, Theories, and Practices

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Overview of Naturopathic Regulation

Colorado Department of Regulatory Agencies
October 14, 2005

The legal status of naturopathy varies from state to state. In some states, the practice of naturopathy, though not regulated, is protected through court rulings or attorney general opinions. In most states, naturopathic physician status is unprotected or unclear. Two states, Florida and Nevada, have repealed regulation of this profession. Nevada ceased licensing naturopathic physicians in 1987 (in Nevada naturopathic physicians were required to be supervised by medical doctors). Although naturopathic licensing in Florida was discontinued in 1959, there are still laws and a board regulating those naturopaths still practicing. Florida allows naturopathic physicians licensed prior to program termination dates to continue to practice. In Tennessee and in South Carolina, the practice of naturopathy is illegal. Tennessee law, for example, provides that the practice of naturopathy is a Class B misdemeanor, but renders this prohibition inapplicable to "persons who comply with the regulatory laws of the state with respect to the practice of the various healing arts." Without a similar textual qualification, however, a South Carolina statute prohibits the practice of naturopathy and subjects offenders to a fine not to exceed $500 or imprisonment for a period not exceeding one year, or both.

The multiplicity of therapies and techniques that typically comprise the statutory definition of naturopathy may often fall within the scope of practice for other professions. The Montana Naturopathic Practice Act expressly acknowledges this fact by recognizing that many of the therapies used by naturopathic physicians, such as the use of nutritional supplements, herbs, foods, homeopathic preparations, and such physical forces as heat, cold, water, touch, and light, are not the exclusive privilege of naturopathic physicians, and their use, practice, prescription, or administration by persons not licensed to practice naturopathic medicine is not prohibited by this practice act.

Currently, 15 states and the District of Columbia license naturopathic physicians: Alaska, Arizona, California, Connecticut, Florida, Hawaii, Idaho, Kansas, Maine, Montana, New Hampshire, Oregon, Utah, Vermont, and Washington. In several states, licensed naturopathic physicians must also qualify for a certificate to practice natural childbirth, acupuncture, or to dispense a natural substance or device. The following highlights the regulatory programs found in the 15 states.

Alaska

Alaska's law places several restrictions on the practice of naturopathy. A person who practices naturopathy may not prescribe a prescription drug, perform surgery, or use the word "physician" as a title. There are currently 36 licensed naturopathic doctors in Alaska.

Arizona

Arizona's Naturopathic Physicians Board of Medical Examiners (Arizona Board) was established in 1935. Arizona remains the state with the third highest number of licensed naturopathic physicians (400). The Arizona Board has the statutory authority to adopt rules for recognizing naturopathic specialties. The Arizona Board has approved training programs in four specialty areas and has issued certificates to at least 16 naturopaths in the specialty of family medicine. Additionally, the Arizona Board has assembled a formulary of more than 460 items that naturopathic physicians may dispense including both prescription drugs and some controlled substances. In 2000, the Arizona Board underwent a performance audit. The review concluded that terminating the Arizona Board would not significantly harm the public's health and safety since the practice of medicine would continue to be regulated by the Allopathic Board of Medical Examiners. Naturopaths could continue to perform many traditional activities, but would no longer be allowed to act as primary medical care providers. However, the review further stated that terminating the Arizona Board could harm the public's welfare by potentially limiting access to alternative medical care. Subsequently, there was no action taken by the Arizona legislature to repeal the Arizona Board.

California

California's Bureau of Naturopathic Medicine (Bureau) within the Department of Consumer Affairs was established to administer the Naturopathic Doctor's Act and was authorized to collect fees and receive license applications beginning January 1, 2004. This act authorizes the creation of an advisory committee comprised of three licensed naturopathic doctors, three licensed physicians, and three public members. The committee's first meeting was convened on December 13, 2004. Additionally, a naturopathic formulary advisory committee was formed and a naturopathic childbirth attendance advisory committee was created to issue recommendations concerning the practice of naturopathic childbirth attendance. The scope of practice for licensed naturopathic doctors includes diagnosis and treatment of patients, including the authority to order lab tests and prescribe most drugs subject to supervision of a medical or osteopathic physician. Licensed naturopathic doctors may perform minor procedures, such as treating lacerations and removing moles and growths. The program began accepting license applications in January 2005. Currently there are 129 licensed naturopathic doctors in California.

Connecticut

Connecticut's law, which was enacted in 1920, does not allow licensed naturopathic physicians to perform minor surgery, prescribe drugs, or practice obstetrics and gynecology. The statute requires that naturopathic physicians maintain professional liability insurance. There are currently 196 licensed naturopaths in Connecticut.

District of Columbia

In May 2004, final approval was given to the Naturopathic Medicine Licensing Amendment Act of 2004 to license naturopathic physicians as primary care providers. The act recognized naturopathic physicians who have completed four-years of naturopathic medical college training and successfully passed the NPLEX. Prior to the passage of this act, the District of Columbia had a registration program for naturopaths. A person registered to practice naturopathy was entitled to use the title "Doctor of Naturopathy." The only requirements for registration were that applicants must be at least 18 years of age and not have been convicted of a crime of moral turpitude that bears directly on the applicant's fitness to be registered. The practice specifically excluded the use of x-rays, performing any surgical procedure, injecting any substance into a person by needle, or performing any invasive procedure. As of September 2005, the District of Columbia had not promulgated any rules or issued any licenses.

Florida

Florida's licensing authority for naturopathic physicians was abolished in 1959 and licensees who were licensed at that time were allowed to continue practicing naturopathic medicine. Draft legislation proposed by the Florida Naturopathic Physician Association was introduced in 2004 to reestablish regulation of naturopathic medicine through licensure and to create the Board of Naturopathic Medicine within the Department of Health. A 2004 Sunrise Report on Proposed Licensure of Naturopathic Physicians, by the Florida House of Representatives, Committee on Health Care, concluded that while there is evidence for support of licensure based on the existence of accredited training programs and licensure examinations, there is no documented evidence of substantial risk from not licensing naturopathic physicians. Moreover, there is potential risk from licensing naturopathic physicians and allowing them to provide a broad range of primary care services.

Hawaii

Hawaii has regulated naturopathic physicians since 1925. There are currently 81 licensed naturopaths. Originally, the Board of Health was responsible for conducting examinations and issuing licenses. In 1969, the regulation was transferred to the Department of Regulatory Agencies, now the Department of Commerce and Consumer Affairs. The regulation of naturopathy was reviewed in 1978 and 1985, with continued regulation recommended in both instances.

Idaho

Idaho became the 15th state in 2005 to create a licensure program for naturopathic physicians. The legislation is a full scope and title protection act. The law requires the creation of a formulary council to determine pharmaceutical privileges for naturopathic physicians.

Kansas

Kansas passed legislation during the 2002 legislative session to regulate the practice of naturopathic medicine. The bill, signed into law in May 2003, provides registration for naturopathic doctors, rather than licensing, yet requires educational and testing requirements. Naturopathic medicine is defined to include such procedures as venipuncture, naturopathic

acupuncture, and minor office procedures. Naturopathic doctors may not perform surgery, practice obstetrics, administer ionizing radiation or prescribe, dispense or administer any controlled substances or any prescription-only drugs except those listed on the naturopathic formulary adopted by the Kansas board.

Maine

Maine's Board of Complimentary Health Care Providers regulates 19 naturopathic doctors. Naturopathic doctors have the exclusive right to the use of the terms "naturopathic doctors," "naturopathic," "naturopath," "doctor of naturopathic medicine," "Doctor of Naturopathy," "naturopathic medicine," "naturopathic health care," "naturopathy," and "N.D." Use of the term "physician" by a licensee is prohibited. Naturopathic Doctors have a limited scope of prescriptive authority.

Montana

Montana's Naturopathic Health Care Practice Act was enacted in 1991 to regulate lay midwives and naturopathic physicians. Naturopathic physicians are authorized to perform minor surgery, attend a natural childbirth if in possession of a certificate of specialty practice, and prescribe certain drugs as established by the natural substance formulary list. When the program first began there were only five licensed naturopathic physicians in the state, however, as of August 2005, there were 66.

New Hampshire

New Hampshire's Naturopathic Health Care Practice Act was enacted in 1994. Specialty certificates in naturopathic childbirth and acupuncture are offered. Doctors of naturopathic medicine with specialty certification in naturopathic childbirth are authorized to use oxytocin and pitocin. There are currently 36 licensed naturopathic physicians in New Hampshire.

Oregon

Oregon first began licensing naturopathic physicians in 1927, although they were able to practice before then under an exemption in the Osteopathic Practice Act. The total number of licensed naturopathic physicians in Oregon equals 636, ranking second for licensees in a state. Oregon also has the most encompassing law as practitioners are allowed to prescribe drugs, perform minor surgery, and practice natural childbirth with a certificate of special competency.

Utah

Utah's Naturopathic Physicians Licensing Board was created in 1996. The board currently issues five different categories of licenses: naturopath, naturopath including surgery/obstetrics, naturopathic physician, temporary naturopathic physician, and naturopathic controlled substance. In order to perform naturopathic childbirth, a licensee must satisfy the standards of the American College of Naturopathic Obstetricians or its successor.

Vermont

Vermont's licensed naturopathic physicians may order, prescribe, dispense, and administer certain medications of mineral, animal, or botanic origin and must adhere to the Naturopathic Physician Formulary Rules promulgated by the Vermont Department of Health. Licensees may not practice naturopathic childbirth unless they have obtained a special endorsement that requires specific education; training; passage of an examination; and actual childbirth assistance, participation, and observation.

Washington

Washington has regulated naturopathic physicians since 1919, as part of its law created to regulate professions engaged in "drugless healing." The law was substantially amended in 1988 to reflect the current practice of naturopathic physicians. The total number of licensed naturopathic physicians in Washington is 650, ranking first for licensees in a state.

This article was extracted from the Sunrise Review of Naturopathic Physicians, published by the Colorado Department of Regulatory Agencies' Office of Policy, Research and Regulatory Reform in October 2005.

This article was posted on November 20, 2005.

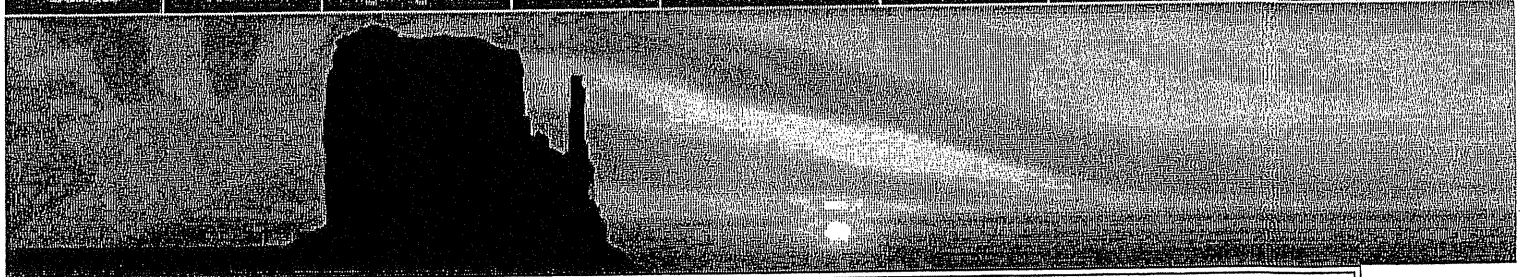
OR

850-060-0225 **Effective December 12, 2005**

Naturopathic Formulary Compendium

The following substances have been recommended for addition to the Formulary Compendium after review by the Board of Naturopathic Examiners Formulary Council established by the 65th Oregon Legislature. Substances listed on the formulary compendium can be prescribed in any dosage or any dosage form. Products marked with an asterisk (*) may be used by Naturopathic Physicians, but may not be prescribed. Combination products containing only active ingredients listed in the Formulary may be prescribed. Combination products containing any active ingredient(s), not listed in the Formulary, except non-legend drugs, may not be prescribed.

(1) Abacavir;
(2) Acarbose;
(3) Acetic Acid;
(4) Acetylcysteine;
(5) Acitretin;
(6) Acyclovir;
(7) Adapalene;
(8) Adenosine Monophosphate;
(9) Albuterol Sulfate;
(10) Alendronate;
(11) Allopurinol;
(12) Alprostadil;
(13) Amino Acids;
(14) Amino Aspirins;
(15) Aminoglycosides;
(16) Aminolevulinic Acid;
(17) Aminophylline;
(18) Aminosalicylic Acid;
(19) Ammonium Chloride;
(20) Ammonium lactate lotion 12%;
(21) Amoxicillin;
(22) Amoxicillin & Clavulanate;
(23) Amphotericin B;
(24) Ampicillin;
(25) Ampicillin & Sulbactam;
(26) Anastrozole;
(27) Anthralin;
(28) Atorvastatin;
(29) Atropine;
(30) Atropine Sulfate;
(31) Auranofin;
(32) Azelaic Acid;
(33) Azithromycin;
(34) Bacampicillin;
(35) Bacitracin;
(36) Baclofen;
(37) Becaplermin;
(38) Belladonna;
(39) Benazepril;
(40) Benzodiazepines;
(41) Benzoic Acid;
(42) Benzonatate;
(43) Betaine;
(44) Betamethasone;
(45) Bethanechol Chloride;
(46) Bichloracetic Acid*;
(47) Bimatoprost Solution 0.03%;
(48) Biologicals;
(49) Biphosphonate;
(50) Bromocriptine;
(51) Budesonide;
(52) Buprenorphine;
(53) Butorphanol;
(54) Cabergoline;
(55) Calcipotriene;
(56) Calcitonin;
(57) Calcitriol;
(58) Carbamide Peroxide;
(59) Carbidopa;
(60) Carbol-Fuchsin;
(61) Captopril;
(62) Cefaclor;
(63) Cefdinir;
(64) Cefibuten;
(65) Cefadroxil;
(66) Cefditoren;
(67) Cefixime;
(68) Cefonicid Sodium;
(69) Cefpodoxime Proxetil;
(70) Cefprozil;
(71) Ceftibuten;
(72) Cefuroxime;
(73) Celecoxib;
(74) Cellulose Sodium Phosphate;
(75) Cenestin;
(76) Cephalexin;



32-1522. Basic qualifications for license

A. To be eligible for a license to practice naturopathic medicine pursuant to this chapter, the applicant shall:

1. Be a graduate of an approved school of naturopathic medicine.

2. Have satisfactorily completed an approved internship, preceptorship or clinical training program in naturopathic medicine.

3. Possess a good moral and professional reputation.

4. Be physically and mentally fit to practice as a doctor of naturopathic medicine.

5. Not be guilty of any act of unprofessional conduct or any other conduct that would be grounds for refusal, suspension or revocation of a license under this chapter.

6. Not have had a license to practice any profession refused, revoked or suspended by any other state, district or territory of the United States or another country for reasons that relate to the applicant's ability to skillfully and safely practice as a physician in this state.

7. File a completed application pursuant to section 32-1524 and meet the examination requirements provided for in section 32-1525.

B. The board may:

1. Require an applicant to submit credentials or other written or oral proof.

2. Make investigations it deems proper to adequately advise itself with respect to the qualifications of an applicant.

C. Within ninety days after it receives a completed application for initial licensure, the board shall issue a license if the application demonstrates to the board's satisfaction that the applicant complies with this chapter and board rules.

32-1501. Definitions

In this chapter, unless the context otherwise requires:

1. "Accepted therapeutic purpose" means treatment of a disease, injury, ailment or infirmity that is competent and generally recognized as safe and effective.

2. "Active license" means a current valid license to practice naturopathic medicine.

3. "Adequate medical records" means medical records containing sufficient information to identify the patient, the diagnosis and the treatment prescribed.

4. "Approved clinical training program" or "clinical training program" means a program for naturopathic medical students in which the training occurred or is being conducted by or in conjunction with an approved school of naturopathic medicine.

5. "Approved internship program" or "internship" means that the program in which the training occurred or is being conducted has been approved for internship training for physicians or for graduates of a school of naturopathic medicine by the board or was approved or accredited by an educational or professional association recognized by the board or by another state's or country's licensing agency recognized by the board.

6. "Approved postdoctoral training" or "postdoctoral training" means that the program in which the training occurred or is being conducted has been approved for specialty training or for graduate medical education in naturopathic medicine by the board or approved or accredited by an educational or professional association recognized by the board or by another state's or country's licensing agency recognized by the board.

7. "Approved preceptorship program" or "preceptorship" means that the program in which the training occurred or is being conducted has been approved for preceptorship training for physicians or for graduates of a school of naturopathic medicine by the board or was approved or accredited by an educational or professional association recognized by the board or by another state's or country's licensing agency recognized by the board.

8. "Approved school of naturopathic medicine" or "school of naturopathic medicine" means a school or college determined by the board to have an educational program that meets standards prescribed by the council on naturopathic medical education, or its successor agency, and that offers a course of study that, on successful completion, results in the awarding of the degree of doctor of naturopathic medicine and whose course of study is either of the following:

(a) Accredited or a candidate for accreditation by an accrediting agency recognized by the United States secretary of education as a specialized accrediting agency for schools of naturopathic medicine or its successor.

(b) Accredited or a candidate for accreditation by an accrediting agency recognized by the council for higher education accreditation or its successor.

9. "Board" means the naturopathic physicians board of medical examiners.

10. "Chelation therapy" means an experimental medical therapy to restore cellular homeostasis through the use of intravenous, metal-binding and bioinorganic agents such as ethylene diamine tetraacetic acid. Chelation therapy does not include experimental therapy used to treat heavy metal poisoning.

11. "Completed application" means that the applicant paid the required fees and supplied all documents and information as requested by the board and in a manner acceptable to the board.

12. "Controlled substance" means a drug, substance or immediate precursor in schedules I through V of title 36, chapter 27, article 2.

13. "Direct supervision" means that a physician who is licensed pursuant to this chapter or chapter 13, 17 or 29 of this title:

(a) Is physically present and within sight or sound of the person supervised and is available for consultation regarding procedures that the physician has authorized and for which the physician remains responsible.

(b) Has designated a person licensed pursuant to this chapter or chapter 13, 17 or 29 of this title to provide direct supervision in the physician's absence.

14. "Doctor of naturopathic medicine" or "doctor" means a natural person licensed to practice naturopathic medicine under this chapter.

15. "Drug" has the same meaning prescribed in section 32-1901 but does not include:

(a) Intravenous administration of legend drugs, except for:

(i) Vitamins, chelation therapy and drugs used in emergency resuscitation and stabilization.

(ii) Minerals.

(b) Controlled substances listed as schedule I or II controlled substances as defined in the federal controlled substances act of 1970 (21 United States Code section 802), except morphine and any homeopathic preparations that are also controlled substances.

(c) Cancer chemotherapeutics classified as legend drugs.

(d) Antipsychotics.

16. "General supervision" means that the physician is available for consultation regarding procedures that the physician has authorized and for which the physician remains responsible.

17. "Legend drug" means any drug defined by section 503(b) of the federal food, drug and cosmetic act and under which definition its label is required to bear the statement "Rx only".

18. "Letter of concern" means a nondisciplinary advisory letter that is issued by the board to a person who is regulated under this chapter and that states that while there is insufficient evidence to support disciplinary action the board believes that the person should modify or eliminate certain practices and that continuation of the activities that led to the information being submitted to the board may result in action against the person's license, certificate or registration.

19. "Letter of reprimand" means a disciplinary letter that is issued by the board and that informs a person who is regulated under this chapter that the person's conduct violates state or federal law but does not require the board to restrict the person's license, certificate or registration because the person's conduct did not result in harm to a patient or to the public.

20. "Limit" means taking a nondisciplinary action that alters the physician's practice or professional activities if the board determines that there is evidence that the physician is or may be mentally or physically unable to safely engage in the practice of medicine.

21. "Medical assistant" or "naturopathic medical assistant" means a person who is certified by the board as a medical assistant, who assists a doctor of naturopathic medicine and who may perform delegated procedures that are commensurate with the assistant's education and training under the direct supervision of a doctor of naturopathic medicine and that do not include diagnosing, designing or modifying established treatment programs or those procedures prohibited by the board or by this chapter.

22. "Medically incompetent" means a person who is licensed, certified or registered pursuant to this chapter and who lacks sufficient naturopathic medical knowledge or skills, or both, to a degree that is likely to endanger the health of patients.

23. "Naturopathic medical student" means a person who is enrolled in a course of study at an approved school of naturopathic medicine.

24. "Naturopathic medicine" means medicine as taught in approved schools of naturopathic medicine and in clinical, internship, preceptorship and postdoctoral training programs approved by the board and practiced by a recipient of a degree of doctor of naturopathic medicine licensed pursuant to this chapter.

25. "Nurse" means a person licensed pursuant to chapter 15 of this title.

26. "Physician" means a doctor of naturopathic medicine licensed pursuant to this chapter.

27. "Practice of naturopathic medicine" means a medical system of diagnosing and treating diseases, injuries, ailments, infirmities and other conditions of the human mind and body including by natural means, drugless methods, drugs, nonsurgical methods, devices, physical, electrical, hygienic and sanitary measures and all forms of physical agents and modalities.

28. "Restrict" means taking a disciplinary action that alters the physician's practice or professional activities if the board determines that there is evidence that the physician is or may be medically incompetent or guilty of unprofessional conduct.

29. "Specialist" means a physician who has successfully completed approved postdoctoral training, who is certified by a specialty board of examiners recognized by the board and who is certified by the board to practice the specialty pursuant to this chapter.

30. "Unprofessional conduct" includes the following, whether occurring in this state or elsewhere:

(a) Intentionally disclosing a professional secret or intentionally disclosing a privileged communication except as either of these may otherwise be required by law.

(b) Any dishonorable conduct reflecting unfavorably on the profession.

(c) Committing a felony, whether or not involving moral turpitude, or a misdemeanor involving moral turpitude. In either case conviction by any court of competent jurisdiction or a plea of no contest is conclusive evidence of the commission of the felony or misdemeanor.

(d) Habitual intemperance in the use of alcohol or any substance abuse.

(e) The illegal use of any narcotic or hypnotic drugs, or illegal substances.

(f) Conduct that the board determines is gross malpractice, repeated malpractice or any malpractice resulting in the death of a patient.

(g) Impersonating another doctor of naturopathic medicine or any other practitioner of the healing arts.

(h) Falsely acting or assuming to act as a member, an employee or an authorized agent of the board.

(i) Procuring or attempting to procure a license or a certificate pursuant to this chapter by fraud, by misrepresentation or by knowingly taking advantage of the mistake of another person or agency.

(j) Having professional connection with or lending one's name to enhance or continue the activities of an illegal physician or an illegal practitioner of any healing art.

(k) Representing that a manifestly incurable disease, injury, ailment or infirmity can be permanently cured, or falsely or fraudulently representing that a curable disease, injury, ailment or infirmity can be cured within a stated time.

(l) Offering, undertaking or agreeing to cure or treat a disease, injury, ailment or infirmity by a secret means, method, treatment, medicine, substance, device or instrumentality.

(m) Refusing to divulge to the board on demand the means, method, treatment, medicine, substance, device or instrumentality used in the treatment of a disease, injury, ailment or infirmity.

(n) Giving or receiving, or aiding or abetting the giving or receiving of, rebates, either directly or indirectly.

(o) Knowingly making any false or fraudulent statement, written or oral, in connection with the practice of naturopathic medicine or any naturopathic treatment method.

(p) Immorality or misconduct that tends to discredit the naturopathic profession.

(q) Refusal, revocation or suspension of a license by any other state, district or territory of the United States or any other country, unless it can be shown that this action was not due to reasons that relate to the ability to safely and skillfully practice as a doctor of naturopathic medicine or to any act of unprofessional conduct in this paragraph.

(r) Any conduct or practice that is contrary to recognized standards of ethics of the naturopathic profession, any conduct or practice that does or might constitute a danger to the health, welfare or safety of the patient or the public, or any conduct, practice or condition that does or might impair the ability to safely and skillfully practice as a doctor of naturopathic medicine.

(s) Failure to observe any federal, state, county or municipal law relating to public health as a physician in this state.

(t) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of, or conspiring to violate any of the provisions of this chapter or board rules.

(u) False, fraudulent, deceptive or misleading advertising or advertising the quality of a medical or health care service by a physician or by the physician's staff, employer or representative.

(v) Failing or refusing to maintain adequate medical records on a patient or failing or refusing to make medical records in the physician's possession promptly available to another physician or health care provider who is licensed pursuant to chapter 7, 8, 13, 15, 17 or 29 of this title on request and receipt of proper authorization to do so from the patient, a minor patient's parent, the patient's legal guardian or the patient's authorized representative or failing to comply with title 12, chapter 13, article 7.1.

(w) Referring a patient to a diagnostic or treatment facility or prescribing goods and services without disclosing in writing to the patient that the physician has a pecuniary interest in the facility, goods or services to which the patient is referred or prescribed. This subdivision does not apply to a referral by one physician or practitioner to another physician or practitioner within a group of physicians or practitioners practicing together.

(x) Sexual intimacies with a patient in the course of direct treatment.

(y) Failing to dispense drugs and devices in compliance with article 4 of this chapter.

(z) Administering, dispensing or prescribing any drug or a device for other than an accepted therapeutic purpose.

(aa) Falsely representing or holding oneself out as being a specialist or representation by a doctor of naturopathic medicine or the doctor's staff, employer or representative that the doctor is boarded or board certified if this is not true or that standing is not current.

(bb) Delegating professional duties and responsibilities to a person if the person has not been approved or qualified by licensure or by certification to perform these duties or responsibilities.

(cc) Failing to appropriately supervise a naturopathic medical student, a nurse, a medical assistant, a health care provider or a technician employed by or assigned to the physician during the performance of delegated professional duties and responsibilities.

(dd) Using experimental forms of diagnosis or treatment without adequate informed consent of the patient or the patient's legal guardian and without conforming to experimental criteria including protocols, detailed records, periodic analysis of results and periodic review by a medical peer review committee as approved by the federal food and drug administration or its successor agency.

(ee) Failing to furnish information in a timely manner to the board or investigators or representatives of the board if this information is legally requested by the board and failing to allow properly authorized board personnel on demand to examine and have access to

documents, reports and records maintained by the physician that relate to the physician's medical practice or medically related activities.

(ff) Failing to report in writing to the board evidence that a person licensed, certified or registered pursuant to this chapter is or may be medically incompetent, guilty of unprofessional conduct or mentally or physically unable to safely practice or assist in the practice of naturopathic medicine.

(gg) Conducting or engaging in an internship, preceptorship or clinical training program in naturopathic medicine without being approved and registered by the board for that internship, preceptorship or clinical training program.

(hh) Signing a blank, undated or predated prescription form.

(ii) Conduct that the board determines is gross negligence, repeated negligence or negligence resulting in harm or death to a patient.

(jj) Knowingly making a false or misleading statement in oral testimony to the board on a form required by the board or in written correspondence to the board, including attachments to that correspondence.

(kk) The failure of a physician who is the chief medical officer, the executive officer or the chief of staff of an internship, a preceptorship or a clinical training program to report in writing to the board that the privileges of a doctor of naturopathic medicine, a naturopathic medical student or a medical assistant have been denied, limited, revoked or suspended because that doctor's, student's or assistant's actions appear to indicate that the person is or may be medically incompetent, is or may be guilty of unprofessional conduct or is or may be unable to safely engage or assist in the practice of naturopathic medicine.

(ll) Action taken against a doctor of naturopathic medicine by a licensing or regulatory board in another jurisdiction due to that doctor's mental or physical inability to engage safely in the practice of naturopathic medicine, the doctor's medical incompetence or for unprofessional conduct as defined by that licensing or regulatory board and that corresponds directly or indirectly to an act of unprofessional conduct prescribed by this paragraph. The action taken may include refusing, denying, revoking or suspending a license, otherwise limiting, restricting or monitoring a licensee or placing a licensee on probation by that licensing or regulatory board.

(mm) Sanctions imposed by an agency of the federal government, including restricting, suspending, limiting or removing a person from the practice of naturopathic medicine or restricting that person's ability to obtain financial remuneration.

(nn) Violating any formal order, probation, consent agreement or stipulation issued or entered into by the board pursuant to this chapter.

(oo) Refusing to submit to a body fluid examination pursuant to a board investigation of alleged substance abuse by a doctor of naturopathic medicine.

(pp) Charging a fee for services not rendered or dividing a professional fee for patient referrals among health care providers or health care institutions or between these providers and institutions or a contractual arrangement that has this effect.

(qq) Obtaining a fee by fraud, deceit or misrepresentation.

(rr) Charging or collecting a clearly excessive fee. In determining if a fee is clearly excessive the board shall consider the fee or range of fees customarily charged in this state for similar services, in light of modifying factors such as the time required, the complexity of the service and the skill required to perform the service properly. This subdivision does not apply if there is a clear written contract for a fixed fee between the physician and the patient that was entered into before the service was provided.

(ss) With the exception of heavy metal poisoning, using chelation therapy in the treatment of arteriosclerosis or as any other form of therapy without adequate informed patient consent and without conforming to generally accepted experimental criteria, including protocols, detailed records, periodic analysis of results and periodic review by a medical peer review committee.

(tt) Using a controlled substance unless it is prescribed by another physician for use during a prescribed course of treatment.

(uu) Prescribing, dispensing or administering anabolic androgenic steroids for other than therapeutic purposes.

(vv) Except in an emergency or urgent care situation, prescribing or dispensing a controlled substance to a member of the naturopathic physician's immediate family.

(ww) Prescribing, dispensing or furnishing a prescription medication or a prescription-only device as defined in section 32-1901 to a person unless the licensee first conducts a physical examination of that person or has previously established a doctor-patient relationship. This subdivision does not apply to:

(i) A licensee who provides temporary patient supervision on behalf of the patient's regular treating licensed health care professional.

(ii) An emergency medical situation as defined in section 41-1831.

(iii) Prescriptions written to prepare a patient for a medical examination.

(iv) Prescriptions written or prescription medications issued for use by a county or tribal public health department for immunization programs or emergency treatment or in response to an infectious disease investigation, a public health emergency, an infectious disease outbreak or an act of bioterrorism. For the purposes of this item, "bioterrorism" has the same meaning prescribed in section 36-781.

32-1581. Dispensing of natural substances, drugs and devices; conditions; civil penalty; dispensing minerals; definitions

A. A doctor of naturopathic medicine may dispense a natural substance, drug or device to a patient for a condition being diagnosed or treated by the doctor if:

1. The doctor is certified to dispense by the board and the certificate has not been suspended or revoked by the board.

2. The natural substance, drug or device is dispensed and properly labeled with the following dispenser information:

(a) The dispensing doctor's name, address and telephone number and a prescription number or other method of identifying the prescription.

(b) The date the natural substance, drug or device is dispensed.

(c) The patient's name.

(d) The name and strength of the natural substance, drug or device, directions for proper and appropriate use and any cautionary statements for the natural substance, drug or device. If a generic drug is dispensed the manufacturer's name must be included.

3. The dispensing doctor enters into the patient's medical record the name and strength of the natural substance, drug or device dispensed, the date the natural substance, drug or device is dispensed and the therapeutic reason.

4. The dispensing doctor keeps all prescription-only drugs, controlled substances and prescription-only devices in a secured cabinet or room, controls access to the cabinet or room by a written procedure and maintains an ongoing inventory of its contents.

B. Except in an emergency, a doctor of naturopathic medicine who dispenses a natural substance, drug or device without being certified to dispense by the board is subject to a civil penalty by the board of not less than three hundred dollars and not more than one thousand dollars for each transaction and may be prohibited from further dispensing for a period of time as determined by the board.

C. Before dispensing a natural substance, drug or device pursuant to this section, the treating doctor shall give the patient or the patient's legal guardian a written prescription and must inform the patient or the patient's legal guardian that the prescription may be filled by the prescribing doctor or the pharmacy of the patient's choice. If the patient chooses to have the medication dispensed by the doctor, the doctor must retrieve the written prescription and place it in a prescription file kept by the doctor.

D. A doctor of naturopathic medicine shall provide direct supervision of a nurse or attendant involved in the dispensing process. In this subsection, "direct supervision" means that a doctor of naturopathic medicine is present and makes the determination as to the necessary use or the advisability of the natural substance, drug or device to be dispensed.

E. The board shall enforce this section. The board shall adopt rules regarding the dispensing of a natural substance, drug or device including the labeling, record keeping, storage and packaging of natural substances that are consistent with the requirements of chapter 18 of this title. The board may conduct periodic inspections of dispensing practices to assure compliance with this section and applicable rules.

F. This section does not prevent a licensed practical or professional nurse employed by a doctor of naturopathic medicine from assisting in the delivery of natural substances, drugs and devices in accordance with this chapter.

G. Before prescribing or dispensing a mineral to a patient, the treating physician shall perform necessary clinical examinations and laboratory tests to prevent toxicity due to the excessive intake of magnesium, calcium and other minerals. The board shall adopt rules necessary for the safe administration of minerals. These rules shall require prior certification of a physician who prescribes or dispenses minerals to a patient.

H. For the purposes of this section:

1. "Device" means an appliance, apparatus or instrument administered or dispensed to a patient by a doctor of naturopathic medicine.

2. "Dispense" means the delivery by a doctor of naturopathic medicine of a natural substance, drug or device to a patient and only for a condition being diagnosed or treated by that doctor, except for free samples packaged for individual use by licensed manufacturers or repackagers, and includes the prescribing, administering, packaging, labeling and security necessary to prepare and safeguard the natural substance, drug or device for delivery to the treating doctor's own patient.

3. "Natural substance" means a homeopathic, botanical or nutritional supplement that does not require a prescription by federal law before it is dispensed, but is prescribed to treat a medical condition diagnosed by the doctor.

The Oregon Administrative Rules contain OARs filed through August 15, 2006

BOARD OF NATUROPATHIC EXAMINERS

DIVISION 60

PRESCRIBING AUTHORITY; EDUCATION; FORMULARY

850-060-0212

Education Requirements for Injections/ IV Chelation Therapy

1) Before using therapeutic injections of vitamins and minerals, or preventive injections of any substance, whether intramuscular (IM) or subcutaneous (SC) or intravenous (IV), licensee must provide proof of Board approved qualifying continuing education prior to using these applications as set forth in this rule, or proof of Board approved qualifying education received at an approved medical institution equivalent to the prescribed continuing education.

2) Non-IV therapeutic injections of vitamins or minerals require a one-time two hour qualifying education on this subject.

3) IV therapeutic injections of vitamins or minerals require a one-time 12 hour qualifying education on this subject.

4) Preventive injections (IM, SC, IV) require an additional one-time four hours of qualifying education in addition to the CE hours noted in OAR 850-060-0212(2) and (3).

5) The use of any IV chelation therapy requires 12 hours of Board approved qualifying education in addition to the education required in (2), (3) and (4) of this rule.

6) Licensee must stay current in IV chelation training. Current means licensee has completed the education and obtained a certificate of competence within the last five years.

7) Qualifying chelation therapy education must be provided by faculty with at least five years of experience in IV chelation therapy and current training approved by the Board. The qualifying education must contain all of the following:

a) Current/ historical research on IV chelation therapy;

b) Indications/contraindications of IV chelation therapy;

c) IV Chelation therapy side effects and toxicity;

d) IV Chelation therapy and practical application;

e) IV solutions;

f) Initial evaluation and treatment monitoring requirements;

g) Frequency of IV treatment and remineralization;

h) Charting requirements, standards of care, office procedures, consent to treat, nutrition and lifestyle recommendations during treatment;

(i) Heavy metal toxicity and disease;

(j) Practical on mixing and administering IV Chelation solutions;

Attachment 4

California Requirements for Pharmacies Providing Emergency Contraception
and
FDA Materials on Plan B Becoming Available Over the Counter

4052. Furnishing to Prescriber; Permissible Procedures by Pharmacist in Health Care Facility or Clinic or for Other Health Care Provider

(a) Notwithstanding any other provision of law, a pharmacist may:

(1) Furnish a reasonable quantity of compounded medication to a prescriber for office use by the prescriber.

(2) Transmit a valid prescription to another pharmacist.

(3) Administer, orally or topically, drugs and biologicals pursuant to a prescriber's order.

(4) Perform the following procedures or functions in a licensed health care facility in accordance with policies, procedures, or protocols developed by health professionals, including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator:

(A) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(B) Ordering drug therapy-related laboratory tests.

(C) Administering drugs and biologicals by injection pursuant to a prescriber's order (the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility).

(D) Initiating or adjusting the drug regimen of a patient pursuant to an order or authorization made by the patient's prescriber and in accordance with the policies, procedures, or protocols of the licensed health care facility.

(5)(A) Perform the following procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, in accordance, as applicable, with policies, procedures, or protocols of that facility, the home health agency, the licensed clinic, the health care service plan, or that physician, in accordance with subparagraph (C):

(i) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(ii) Ordering drug therapy-related laboratory tests.

(iii) Administering drugs and biologicals by injection pursuant to a prescriber's order (the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility).

(iv) Initiating or adjusting the drug regimen of a patient pursuant to a specific written order or authorization made by the individual patient's treating prescriber, and in accordance with the policies, procedures, or protocols of the health care facility, home health agency, licensed clinic, health care service plan, or physician. Adjusting the drug regimen does not include substituting or selecting a different drug, except as authorized by the protocol. The pharmacist shall provide written notification to the patient's treating prescriber or enter the appropriate information in an electronic patient record system shared by the prescriber, of any drug regimen initiated pursuant to this clause within 24 hours.

(B) A patient's treating prescriber may prohibit, by written instruction, any adjustment or change in the patient's drug regimen by the pharmacist.

(C) The policies, procedures, or protocols referred to in this paragraph shall be developed by health care professionals, including physicians, pharmacists, and registered nurses, and, at a minimum, meet all of the following requirements:

(i) Require that the pharmacist function as part of a multidisciplinary group that includes physicians and direct care registered nurses. The multidisciplinary group shall determine the appropriate participation of the pharmacist and the direct care registered nurse.

(ii) Require that the medical records of the patient be available to both the patient's treating prescriber and the pharmacist.

(iii) Require that the procedures to be performed by the pharmacist relate to a condition for which the patient has first been seen by a physician.

(iv) Except for procedures or functions provided by a health care facility, a licensed clinic in which there is physician oversight, or a provider who contracts with a licensed health care plan with regard to the care or services provided to the enrollees of that health care service plan, require the procedures to be performed in accordance with a written, patient-specific protocol approved by the treating or supervising physician. Any change, adjustment, or modification of an approved preexisting treatment or drug therapy shall be provided in writing to the treating or supervising physician within 24 hours.

(6) Manufacture, measure, fit to the patient, or sell and repair dangerous devices or furnish instructions to the patient or the patient's representative concerning the use of those devices.

(7) Provide consultation to patients and professional information, including clinical or pharmacological information, advice, or consultation to other health care professionals.

(8)(A) Furnish emergency contraception drug therapy in accordance with either of the following:

(i) Standardized procedures or protocols developed by the pharmacist and an authorized prescriber who is acting within his or her scope of practice.

(ii) Standardized procedures or protocols developed and approved by both the board and the Medical Board of California in consultation with the American College of Obstetricians and Gynecologists, the California Pharmacist Association, and other appropriate entities. Both the board and the Medical Board of California shall have authority to ensure compliance with this clause, and both boards are specifically charged with the enforcement of this provision with respect to their respective licensees. Nothing in this clause shall be construed to expand the authority of a pharmacist to prescribe any prescription medication.

(B) Prior to performing a procedure authorized under this paragraph, a pharmacist shall complete a training program on emergency contraception that consists of at least one hour of approved continuing education on emergency contraception drug therapy.

(C) A pharmacist, pharmacist's employer, or pharmacist's agent may not directly charge a patient separate consultation fee for emergency contraception drug therapy services initiated pursuant to this paragraph, but may charge an administrative fee not to exceed ten dollars ($10) above the retail cost of the drug. Upon an oral, telephonic, electronic, or written request from a patient or customer, a pharmacist or pharmacist's employee shall disclose the total retail price that a consumer would pay for emergency contraception drug therapy. As used in this subparagraph, total retail price includes providing the consumer with specific information regarding the price of the emergency contraception drugs and the price of the administrative fee charged. This limitation is not intended to interfere with other contractually agreed-upon terms between a pharmacist, a pharmacist's employer, or a pharmacist's agent, and a health care service plan or insurer. Patients who are insured or covered and receive a pharmacy benefit that covers the cost of emergency contraception shall not be required to pay an administrative fee. These patients

shall be required to pay copayments pursuant to the terms and conditions of their coverage. The provisions of this subparagraph shall cease to be operative for dedicated emergency contraception drugs when these drugs are reclassified as over-the-counter products by the federal Food and Drug Administration.

(D) A pharmacist may not require a patient to provide individually identifiable medical information that is not specified in Section 1707.1 of Title 16 of the California Code of Regulations before initiating emergency contraception drug therapy pursuant to this paragraph.

(b)(1) Prior to performing any procedure authorized by paragraph (4) of subdivision (a), a pharmacist shall have received appropriate training as prescribed in the policies and procedures of the licensed health care facility.

(2) Prior to performing any procedure authorized by paragraph (5) of subdivision (a), a pharmacist shall have either (A) successfully completed clinical residency training or (B) demonstrated clinical experience in direct patient care delivery.

(3) For each emergency contraception drug therapy initiated pursuant to paragraph (8) of subdivision (a), the pharmacist shall provide the recipient of the emergency contraception drugs with a standardized factsheet that includes, but is not limited to, the indications for use of the drug, the appropriate method for using the drug, the need for medical followup, and other appropriate information. The board shall develop this form in consultation with the State Department of Health Services, the American College of Obstetricians and Gynecologists, the California Pharmacists Association, and other health care organizations. The provisions of this section do not preclude the use of existing publications developed by nationally recognized medical organizations.

(c) A pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy pursuant to this section shall personally register with the federal Drug Enforcement Administration.

(d) Nothing in this section shall affect the requirements of existing law relating to maintaining the confidentiality of medical records.

(e) Nothing in this section shall affect the requirements of existing law relating to the licensing of a health care facility.

(Amended Stats. 2004, Chapter 191)

4052.1. Skin Puncture by Pharmacist; Conditions Permitting

Notwithstanding Section 2038 or any other provision of law, a pharmacist may perform skin puncture in the course of performing routine patient assessment procedures or in the course of performing any procedure authorized under Section 1206.5. For purposes of this section, "routine patient assessment procedures" means: (a) procedures that a patient could, with or without a prescription, perform for himself or herself, or (b) clinical laboratory tests that are classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) and the regulations adopted thereunder by the federal Health Care Financing Administration, as authorized by paragraph (11) of subdivision (a) of Section 1206.5. A pharmacist performing these functions shall report the results obtained from a test to the patient and any physician designated by the patient. Any pharmacist who performs the service authorized by this section shall not be in violation of Section 2052.

(Added Stats. 2001, Chapter 501)

prescriber. The pharmacist may not supply the drug after 72 hour period has expired without a new prescription.

(Amended Effective 10-7-2005)

1746. Emergency Contraception

(a) A pharmacist furnishing emergency contraception pursuant to Section 4052(a)(8)(A)(ii) of the Business and Professions Code shall follow the protocol specified in subdivision (b) of this section.

(b) Protocol for Pharmacists Furnishing Emergency Contraception (EC).

(1) Authority: Section 4052 of the California Business and Professions Code authorizes a pharmacist to furnish emergency contraception pursuant to a protocol approved by the Board of Pharmacy and the Medical Board of California. Use of the following protocol satisfies that requirement.

(2) Purpose: To provide access to emergency contraceptive medication within required limits and ensure that the patient receives adequate information to successfully complete therapy.

(3) Procedure: When a patient requests emergency contraception the pharmacist will ask and state the following:

Are you allergic to any medications?

Timing is an essential element of the product's effectiveness. EC should be taken as soon as possible after unprotected intercourse. Treatment may be initiated up to five days (120 hours) of unprotected intercourse. EC effectiveness declines gradually over five days and EC use will not interfere with an established pregnancy.

(4) The pharmacist shall provide the fact sheet and review any questions the patient may have regarding EC. In addition, the pharmacist shall collect the information required for a patient medication record by Section 1707.1 of Title 16 of the California Code of Regulations.

Fact Sheet: The pharmacist will provide the patient with a copy of the current EC fact sheet approved by the Board of Pharmacy as required by Business and Professions Code Section 4052(b)(3).

(5) Referrals and Supplies: If emergency contraception services are not immediately available at the pharmacy or the pharmacist declines to furnish pursuant to conscience clause, the pharmacist will refer the patient to another emergency contraception provider. The pharmacist shall comply with all state mandatory reporting laws, including sexual abuse laws.

(6) The pharmacist may provide up to 12 non-spermicidal condoms to each Medi-Cal and Family PACT client who obtains emergency contraception.

(7) Advanced provision: The pharmacist may dispense emergency contraception medication for a patient in advance of the need for emergency contraception.

(8) EC Product Selection: The pharmacist will provide emergency contraception medication compatible with product information from the list of products specified in this protocol. This list must be kept current and maintained in the pharmacy. Along with emergency contraception products, the list will include adjunctive medications indicated for nausea and vomiting associated with taking EC. Patients will be provided information concerning dosing and potential adverse effects.

(9) Documentation: Each prescription authorized by a pharmacist will be documented in a patient medication record as required by law.

(10) Training: Prior to furnishing emergency contraception, pharmacists who participate in the protocol must have completed a minimum of one hour of continuing education specific to emergency contraception.

(11) Brands and Doses of Oral Contraceptive Tablets Used for Emergency Contraception.

Dedicated Emergency Contraception

Brand	Manufacturer	Tablets per Dose	Ethinyl Estradiol per Dose (mg)	Levonorgestrel per Dose (mg)**
One Dose Regimen				
Plan B	Women's Capital Corporation	2 tablets	0	1.5
Two Dose Regimens				
Plan B	Women's Capital Corporation	1 tablet per dose	0	0.75
Preven	Gynétics	2 tablets per dose	100	0.50

Oral Contraceptive Pills

Brand	Manufacturer	Tablets per Dose (two doses 12 hours apart*)	Ethinyl Estradiol per Dose (mg)	Levonorgestrel per Dose (mg)**
Levora	Watson	4 white tablets	120	0.60
Ovral	Wyeth	2 white tablets	100	0.50
Ogestrel	Watson	2 white tablets	100	0.50
Nordette	Wyeth	4 light-orange tablets	120	0.60
Tri-Levlen	Berlex	4 yellow tablets	100	0.50
Alesse	Wyeth	5 pink tablets	100	0.50
Avlane	Duramed	5 orange tablets	100	0.50
Triphasil	Wyeth	4 yellow tablets	120	0.50
Levlen	Berlex	4 light-orange tablets	120	0.60
Trivora	Watson	4 pink tablets	120	0.50
Levlite	Berlex	5 pink tablets	100	0.50
Lo/Ovral	Wyeth	4 white tablets	120	0.60

Brand	Manufacturer	Tablets per Dose	Ethinyl Estradiol per Dose (mg)	Levonorgestrel per Dose (mg)**
Low-Ogestrel	Watson	4 white tablets	120	0.60
Ovrette	Wyeth	20 yellow tablets	0	0.75

(12) Anti-nausea Treatment Options for use with Emergency Contraception

Drug	Dose	Timing of Administration
Non-prescription Drugs		
Meclizine hydrochloride (Dramamine II, Bonine)	One or two 25 mg tablets	1 hour before first EC dose repeat if needed in 24 hours
Diphenhydramine hydrochloride (Benadryl)	One or two 25 mg tablets or capsules.	1 hour before first EC dose; repeat as needed every 4-6 hours
Dimenhydrinate (Dramamine)	One or two 50 mg tablets or 4-8 teaspoons liquid	30 minutes to 1 hour before first ECP dose; repeat as needed every 4-6 hours
Cyclizine hydrochloride (Marezine)	One 50 mg tablet	30 minutes before first EC dose; repeat as needed every 4-6 hours

(New section filed 11-2-2004; operative 12-2-2004 (Register 2004, No. 45). For prior history, see Register 80, No. 8)

Article 6. Fees and Penalties

(Renumbered from Article 7, 9-11-2002)

1749. Fee Schedule

The fees for the issuance and renewal of licenses, certificates, and permits, and the penalties to be assessed for failure to renew in accordance with section 4400 of the Business and Professions Code are hereby fixed as follows:

(a) The fee for the issuance of a pharmacy license is three hundred forty dollars ($340). The fee for the annual renewal of pharmacy license is one hundred seventy-five dollars ($175). The penalty for failure to renew is eighty-seven dollars and fifty cents ($87.50).

(b) The fee for the issuance of a temporary license is one hundred seventy-five dollars ($175).

(c) The fee for the issuance of a pharmacy technician license shall be fifty dollars ($50). The fee for the biennial renewal of a pharmacy technician license shall be fifty dollars ($50). The penalty for failure to renew a pharmacy technician license is twenty-five dollars ($25).

(d) The fee for application and examination as a pharmacist is one hundred fifty-five dollars ($155).

(e) The fee for regrading an examination is seventy-five dollars ($75).

FDA News

FOR IMMEDIATE RELEASE
P06-118
August 24, 2006

Media Inquiries:
Julie Zawisza, 301-827-6242
Consumer Inquiries:
888-INFO-FDA

FDA Approves Over-the-Counter Access for Plan B for Women 18 and Older
Prescription Remains Required for Those 17 and Under

The U.S. Food and Drug Administration (FDA) today announced approval of Plan B, a contraceptive drug, as an over-the-counter (OTC) option for women aged 18 and older. Plan B is often referred to as emergency contraception or the "morning after pill." It contains an ingredient used in prescription birth control pills--only in the case of Plan B, each pill contains a higher dose and the product has a different dosing regimen. Like other birth control pills, Plan B has been available to all women as a prescription drug. When used as directed, Plan B effectively and safely prevents pregnancy. Plan B will remain available as a prescription-only product for women age 17 and under.

Duramed, a subsidiary of Barr Pharmaceuticals, will make Plan B available with a rigorous labeling, packaging, education, distribution and monitoring program. In the CARE (Convenient Access, Responsible Education) program Duramed commits to:

- Provide consumers and healthcare professionals with labeling and education about the appropriate use of prescription and OTC Plan B, including an informational toll-free number for questions about Plan B;
- Ensure that distribution of Plan B will only be through licensed drug wholesalers, retail operations with pharmacy services, and clinics with licensed healthcare practitioners, and not through convenience stores or other retail outlets where it could be made available to younger women without a prescription;
- Packaging designed to hold both OTC and prescription Plan B. Plan B will be stocked by pharmacies behind the counter because it cannot be dispensed without a prescription or proof of age; and
- Monitor the effectiveness of the age restriction and the safe distribution of OTC Plan B to consumers 18 and above and prescription Plan B to women under 18.

Today's action concludes an extensive process that included obtaining expert advice from a joint meeting of two FDA advisory committees and providing an opportunity for public comment on issues regarding the scientific and policy questions associated with the application to switch Plan B to OTC use. Duramed's application raised novel issues regarding simultaneously marketing both prescription and non-prescription Plan B for emergency contraception, but for different populations, in a single package.

The agency remains committed to a careful and rigorous scientific process for resolving novel issues in order to fulfill its responsibility to protect the health of all Americans.

For more information on Plan B and today's action, please see:
http://www.fda.gov/cder/drug/infopage/planB/default.htm.

Plan B: Questions and Answers
August 24, 2006

1. What is FDA announcing today?

FDA is announcing the approval of the emergency contraceptive drug Plan B as an over-the-counter (OTC) option for women aged 18 and older. A prescription-only form of Plan B will remain available for young women aged 17 and younger.

2. What is emergency contraception?

Emergency contraception is a method of preventing pregnancy after a contraceptive fails or after unprotected sex. It is not for routine use. These pills contain higher levels of a hormone found in daily oral hormonal contraceptives. FDA has approved two products for this prescription use – Preven (approved in 1998 but is no longer being marketed) and Plan B (approved in 1999).

3. What is Plan B?

Plan B is emergency contraception, a backup method to birth control. It is in the form of two levonorgestrel pills (0.75 mg in each pill) that are taken by mouth after a contraceptive fails or after unprotected sex. Levonorgestrel is a synthetic hormone used in birth control pills for over 35 years. Plan B can reduce the chances of a woman becoming pregnant when taken as directed if she has had unprotected sex. Prior to this action, Plan B was available only by prescription.

4. How does Plan B work?

Plan B works like other oral birth control pills to prevent pregnancy. Plan B acts primarily by stopping the release of an egg from the ovary (ovulation). It may prevent the union of sperm and egg (fertilization).

5. Are there any side effects?

According to reports from clinical trials, some women will experience non-serious side effects, such as nausea, stomach pain, headache, dizziness, or breast tenderness. These are similar to the side effects of regular birth control pills.

6. How should Plan B be administered?

Plan B should be taken orally as soon as possible and within 72 hours of unprotected sex. The second tablet should be taken 12 hours after the first tablet. Data shows Plan B is more effective the sooner treatment is started following unprotected sex.

7. How can I purchase over-the-counter Plan B?

Plan B will only be sold in pharmacies/stores staffed by a licensed pharmacist. In order to purchase Plan B over-the-counter, personal identification showing proof of age (18) is required. Plan B will be available behind the counter at the pharmacy in order to manage both prescription (17 years and under) and OTC (18 years and over) dispensing. This means Plan B will not be sold at gas stations or convenience stores, where other OTC products are routinely available.

8. What should I do if I have questions about Plan B?

If you have questions or need more information about Plan B from the company you should:

- Call the toll free number, 1-800-330-1271
- Visit their website www.go2planB.com

If you want more information about Plan B from FDA:

- Visit our Drug Information web page at: www.fda.gov/cder
- Call Drug Information at: 888-INFO-FDA (888-463-6332)
- Questions regarding previous regulatory actions regarding Plan B can be found on our web site at http://www.fda.gov/cder/drug/infopage/planB/default.htm.

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Date created: August 24, 2006

MEMORANDUM

DATE: 8/23/06

FROM: Dr. Andrew C. Von Eschenbach
Acting Commissioner
United States Food and Drug Administration

TO: NDA 21-045, S-011

SUBJECT: Appropriate age restriction for Plan B®

This memorandum regards Barr Laboratories' (Barr or the sponsor[1]) supplemental new drug application (sNDA) dated April 22, 2003, and Barr's subsequent amendments, including its amended sNDA dated August 17, 2006. Barr's most recent sNDA requests that FDA switch Plan B's prescription (Rx) status to non-prescription for women 18 years of age and older, and to have Plan B® remain Rx for girls under 18 years of age.

In an August 26, 2005 memo written by Dr. Steven Galson, the Director of the Center for Drug Evaluation and Research (CDER), CDER found that for women 17 and older the existing Rx dispensing requirements for Plan B® are not necessary to protect the public health and that an Rx-only to non-prescription switch for those consumers is authorized under 21 U.S.C. 353(b)(3) and 21 CFR 310.200. CDER also determined, however, that Barr had not established that Plan B® could be used safely and effectively by young adolescents – girls 16 and younger – for emergency contraception without the professional supervision of a practitioner licensed by law to administer the drug. As a result of this scientific conclusion (with which I concur), Plan B® may not lawfully be made available without a prescription to this group under section 503(b) of the Federal Food, Drug, and Cosmetic Act.

In considering the difficulty of enforcing an age-based restriction on the availability of this oral hormonal contraceptive, I have concluded that 18 (rather than 17) is the more appropriate cutoff point to best promote and protect the public health. The state-regulated pharmacies that will be dispensing Plan B® under Barr's voluntary CARE℠ program (as well as society as a whole) are more familiar with 18 as a cutoff age. I understand that in all 50 states, 18 is the age of majority (i.e., the legal delineation between minor and adult), and retail outlets, including pharmacies, are familiar with using 18 as the age restriction for the sale of certain products. With regard to drug products, for example, the legal age to purchase FDA approved non-prescription nicotine replacement therapy products is 18. Moreover, I also understand that as a matter of state law many products routinely sold by pharmacies, e.g., tobacco products and non-prescription cough-cold products like pseudoephedrine, are restricted to consumers 18 and older.

[1] The current applicant for the Plan B sNDA is Duramed Research Pharmaceuticals (Duramed), a wholly-owned subsidiary of Barr. For ease of reference, this memo will refer to both entities as Barr.

This approach builds on well-established state and private-sector infrastructures to restrict certain products to consumers 18 and older. Indeed, the agency selected 18 as the appropriate age for non-prescription nicotine replacement therapy products, in part, because the States had already uniformly restricted the sale of tobacco products to those 18 and older. By so doing, FDA was able to utilize the existing state-created infrastructure limiting the sale of tobacco products to minors to ensure the enforcement of its age-based restriction on non-prescription nicotine replacement therapy products. Here, Barr's CARE^{SM} program specifically utilizes state-licensed pharmacies to implement its restricted distribution plan. Given this fact, and the existing experience pharmacies have enforcing the age-based restriction of 18, I have determined that to best protect and promote the public health non-prescription Plan B® should be available for ages 18 and above.

Leveraging well-established state and private-sector infrastructures will allow for comprehensive and effective enforcement of the age-based restrictions. As a result, this approach should minimize the likelihood that younger girls for whom Plan B® has not been found safe and effective for non-prescription use will have access to the product without professional supervision. Therefore, this approach should help ensure safe and effective use of the product.

MEMORANDUM

DATE: August 24, 2006

FROM: Steven Galson, MD, MPH
Director, Center for Drug Evaluation and Research

TO: NDA 21-045, S-011

SUBJECT: Plan B®

I. Introduction

On April 16, 2003, Barr Pharmaceuticals (Barr or the sponsor[1]) submitted a supplement to NDA 21-045 to switch Plan B®, (levonorgestrel) Tablets, 0.75 mg, to over-the-counter (OTC) status. The supplement, S-011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (the Act), was received April 23, 2003. On May 6, 2004, I issued a Not Approvable letter because the supplement did not contain data demonstrating that the product was safe and effective for OTC use by women under age 16.

On July 21, 2004, Barr resubmitted its supplement to NDA 21-045, S-011, seeking to switch Plan B®'s prescription (Rx) status to OTC for women 16 years of age and older, and to have Plan B® remain Rx for women under 16 years of age. This resubmission of July 21, 2004, constituted a complete response to our May 6, 2004, Not Approvable letter. The resubmitted supplemental new drug application proposed to switch Plan B® to OTC status for women ages 16 years or greater and maintenance of prescription status for women under age 16.

On August 26, 2005, then Commissioner Lester M. Crawford, DVM, PhD, sent the sponsor a letter indicating that the Center for Drug Evaluation and Research (CDER) had completed its review of the application, as amended, and had concluded that the available scientific data are sufficient to support the safe use of Plan B® as an OTC product, but only for women who are 17 years of age and older.

The letter went on to state, however, that the Agency was unable, at that time, to reach a decision on the approvability of the application because of unresolved issues that related to the NDA. The letter mentioned three issues: whether the same active ingredient could be marketed both Rx and OTC based solely on the age of the individual using the drug; how, as a practical matter, an age-based distinction could be enforced; and whether the Rx and OTC versions of the same active ingredient may be marketed in a single package. The letter also stated that the agency had decided to ask for public comments on whether we should initiate a rulemaking to codify our interpretation of section 503(b) of the Federal Food, Drug, and Cosmetic Act regarding when an active ingredient can be

[1] The current applicant for the Plan B sNDA is Duramed Research Pharmaceuticals, a wholly-owned subsidiary of Barr. For ease of reference, this memo will refer to both entities as Barr.

simultaneously marketed in both a prescription drug product and an OTC drug product through an advance notice of proposed rulemaking (ANPRM) that published on September 1, 2005 (70 FR 52050). The comment period closed on November 1, 2005, and the agency received about 47,000 comments. The agency hired a contractor to summarize and categorize the comments and the contractor submitted a final report on May 19, 2006.

On July 31, 2006, Dr. Andrew von Eschenbach, Acting Commissioner of Food and Drugs, sent the sponsor a letter indicating that the agency had reviewed the comments received in response to the ANPRM and determined it was not necessary to engage in rulemaking to resolve the novel regulatory issues raised by the application and that we were now proceeding with further evaluation of the application.

CDER staff met with the sponsor on August 8, 2006, and discussed how to address the issues raised in Dr. von Eschenbach's letter regarding the restriction on OTC sales of Plan B® to ages 18 and over, the packaging of prescription and OTC Plan B® in one package, and the Convenient Access Responsible Education (CARE℠) Program.

On August 17, 18, and 23, 2006, the sponsor amended its application to propose revisions to the labeling and to the CARE℠ Program.

II. Approval Standards

FDA must require Rx dispensing of any drug that is not safe for use "except under the supervision of a practitioner licensed by law to administer such drug."[2] A drug sponsor may submit a supplemental application to "switch" a drug that FDA has already approved for Rx use to OTC status. FDA will grant a supplemental application to "switch" when it finds that Rx dispensing is:

> not necessary for the protection of the public health by reason of the drug's toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, and . . . the drug is safe and effective for use in self-medication as directed in proposed labeling.[3]

Such switch applications generally include data from actual use and labeling comprehension studies to demonstrate that the product can be safely and effectively used without the supervision of a practitioner licensed by law to administer the drug. FDA may approve an NDA application only when, among other things, the investigations submitted in the application include adequate tests showing whether or not the drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling and when there is sufficient information to determine from the application whether the drug is safe for use.[4]

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[2] 21 U.S.C. § 353(b)(1).
[3] 21 C.F.R. § 310.200(b).
[4] See 21 U.S.C. § 355(d).

III. Findings

I have completed my review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use under the conditions set forth in the draft labeling submitted August 23, 2006. My previous memoranda on this application (May 6, 2004, and August 25, 2005) describe my reasoning for concluding that Plan B® is safe and effective for OTC use for ages 17 and older, but, in the absence of additional data demonstrating that it is safe and effective for OTC use in women under 17, it must remain Rx for this age group.[5] This memorandum addresses the three issues raised in Dr. von Eschenbach's July 31, 2006 letter: the age 18 restriction, the packaging of the product, and the CARE℠ program.

A. Restriction to Rx Use for Women Under 18

Regarding the restriction on OTC use to age 18 and older, Dr. von Eschenbach decided that this was the appropriate age for OTC use for the reasons described in his memorandum of August 23, 2006. I have read that memorandum and, although I previously concluded that OTC use should be restricted to women 17 or older, I have now determined that for the reasons Dr. von Eschenbach outlines, the approval of this application should reflect a restriction to OTC use for those age 18 and older.

B. Packaging

Regarding the packaging of the Rx and OTC products in a single package, Barr has proposed to package Plan B® in a package that is designed to satisfy both the Rx and OTC labeling requirements. On the front of the package, the statement will appear: "Rx only for age 17 and younger." In addition, the package will have the Drug Facts box required for all OTC products, and will have space for a pharmacist to apply the standard prescription drug labeling before dispensing the product pursuant to a prescription. These proposals make it clear that the product is Rx for age 17 and younger, and OTC for ages 18 and older, satisfying the requirements of section 503(b)(4)(A) of the Act that a drug that is subject to the prescription requirement in section 503(b)(1) bear the "Rx

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[5] As I noted in my August 26, 2005, memo, various CDER reviewers recommended that Plan B® should be switched OTC for the entire population of women who might use the product, including women under age 18. Similar views were expressed by various CDER reviewers in this review cycle (see for example, August 22, 2006, review of the Director, Office of New Drugs, the Director, Office of Nonprescription Products (ONP), and the Acting Director, Office of Drug Evaluation III). For the same reasons described in my August 26, 2005, memo, I do not agree with those recommendations.

I would, however, like to clarify for the record a statement in my August 25, 2005 memo. On page 5, I stated that if Plan B® was used routinely for contraception (a use inconsistent with the labeling), the well-known risks associated with hormonal contraceptives, such as blood clots and stroke, are likely to be higher than with the use of other contraceptives. While it would be inappropriate to use Plan B® for routine contraception because this dose of levonorgestrel has not been shown to be safe and effective for such a use, the relationship between progestin-only oral contraceptives, such as levonorgestrel, and strokes and blood clots has not been fully defined. This clarification does not change my view that the sponsor did not establish that Plan B® can be used safely and effectively by women under 17 without the supervision of a licensed practitioner.

only" symbol. Because section 503(b)(1) applies here, section 503(b)(4)(B), does not. Section 503(b)(4)(B) states: "A drug to which paragraph (1) does not apply shall be deemed to be misbranded if at any time prior to dispensing the label of the drug bears the symbol described in subparagraph (A) [the "Rx only" symbol]."

Furthermore, there are important policy reasons for approving this packaging configuration related to implementing the restriction of the OTC product to ages 18 and over. Because the package will be labeled with the "Rx only" symbol, State and Federal law will require that the packages be dispensed only by pharmacies and other healthcare providers such as physicians and clinics authorized to dispense prescription drugs. The product will not be available through convenience stores and gas stations because they will not be authorized to sell the prescription product. As described in the CARE^{SM} program, wholesale distributors and retail chain drug stores confirmed to the sponsor that they will distribute Plan B® only to licensed pharmacies or heath care clinics. Furthermore, since Plan B® has both Rx and OTC labeling, pharmacies will keep Plan B® behind-the-counter, and either a prescription or government-issued proof of age will be presented before sale of the product.

C. The CARE^{SM} Program

In its July 2004 submission, Barr submitted proposed labeling that included a consumer information leaflet that elaborates on the information contained on the Plan B® outer carton and inner packaging. Among the important information that is included in the consumer information leaflet is information about how Plan B® works, when it is appropriate to use Plan B®, how often it should be used, side effects and warnings, and directions for use. In addition, Barr Laboratories proposed an educational program (Convenient Access Responsible Education Program, CARE^{SM}) with the following elements: (1) labeling, packaging, web site, and informational 24-hour toll-free number, (2) education initiatives for healthcare providers and pharmacists, (3) distribution plans, and (4) monitoring efforts to assess whether the Rx/OTC age distinction is understood and adhered to.

In response to Dr. von Eschenbach's letter of July 31, 2006, describing several issues that he asked be addressed concerning the enforceability of the age restriction, representatives from CDER met with Barr to discuss proposed changes to the CARE^{SM} program to address these concerns. On August 17 and 18, and 23, 2006, Barr submitted amendments to Supplement O11 proposing changes to the CARE^{SM} program.

Specifically, Barr:

- Made changes throughout the program to reflect that Plan B® would be made available only by prescription to women age 17 and younger and would be made available OTC to those age 18 and older who show a government-issued identification of their age.
- Clarified that wholesale distributors and chain drug companies will only distribute Plan B® to licensed pharmacies or other licensed healthcare clinics.
- Clarified that since Plan B® will be labeled as both Rx and OTC, pharmacies will keep the product behind the counter to effectuate the restriction of the OTC

product to ages 18 and older.

- Clarified that if violations of the age restriction are observed, the sponsor will increase its educational efforts regarding the age restriction and focus on improving the level of understanding among pharmacists and pharmacy staff, and will also report repeat violators to the relevant State Boards of Pharmacy.[6]
- Committed to report to FDA the results of its surveys to provide signals of program effectiveness and potential problems, and the point-of-purchase monitoring program to determine whether the Rx requirement for those ages 17 and younger is being adhered to at the point of purchase. These results will be reported to FDA at six-month intervals beginning 30 calendar days after the six-month interval commencing on the date of the approval of the amended sNDA.
- Made additional editorial and clarifying changes to the CARE^{SM} program to reflect changes in packaging.

I have determined that with the changes the sponsor has proposed, the CARE^{SM} program is adequate to support my finding that Plan B® can be safely distributed in the package configuration proposed by Barr.

To ensure that Plan B® will be used safely and effectively by Rx consumers age 17 and below and OTC consumers age 18 and above, the sponsor has agreed to the following activities:

- Monitor trends in the use of emergency contraception to evaluate the effectiveness of the CARE^{SM} program. Specifically, the sponsor agreed to conduct a market research survey or surveys of a subset of healthcare professionals annually, and when practicable, in collaboration with established professional groups. These surveys will be designed to determine whether the Rx requirement for those ages 17 and younger is being adhered to at the point of purchase and to provide signals of program effectiveness and potential problems

[6] I disagree with the recommendation by the Office of Surveillance and Epidemiology (OSE) that the CARE^{SM} program should require the sponsor to notify FDA instead of the State Boards of Pharmacy when pharmacists repeatedly fail to comply with the age restriction (OSE Plan B® CARE^{SM} Program Review Team Review, August 22, 2006). The Director, ONP, accepted OSE's recommendation (Director, ONP Review, August 22, 2006). OSE explained that it believed such a measure of monitoring the compliance with the age restriction was "overly punitive" and may have a negative impact on the availability of this product OTC. OSE states that a lack of pharmacy compliance may be reflective of an inadequate education plan and this information could be used as an opportunity to improve and/or revise the CARE^{SM} program. I disagree that the sponsor's proposal is overly punitive, or that it is proposed as a substitute for adequate education. The CARE^{SM} program states that "findings from the [point-of-purchase] study will be communicated to the pharmacy and the corporate office, if appropriate, since education and retraining will be the first course of remedial action." (CARE^{SM} Program, August 22, 2006, p. 11) The plan states that only in the case of repeat violators will the violator's State Board of Pharmacy be notified. (Id.) Furthermore, these reports to a State Board of Pharmacy do not mean that FDA will not be informed of violations. The CARE^{SM} program provides that the sponsor will report to FDA periodically the findings of the point-of-purchase monitoring program. I believe the sponsor's proposed approach to monitoring will increase the likelihood that pharmacists will dispense Plan B® appropriately, and it is within the sponsor's discretion to propose such action.

associated with consumers' understanding of the purpose and proper use of Plan B®.

- Using relevant survey data regularly collected by others (e.g., Centers for Disease Control's Behavioral Risk Factor Safety Surveillance (CDC BRFSS), Youth Risk Behavior Safety Surveillance (YRBSS)), to monitor for potential indicators that Plan B® is being used in an inappropriate manner. Potential areas of monitoring and reporting include evaluating possible correlations between increases in sexually transmitted infections (STIs) based on geographic areas and data and trends in pregnancy and/or abortion rates based on geographic areas.
- Conduct a "Point-of-Purchase Monitoring Program" to track how Plan B® is being sold at the time of purchase, including using anonymous shoppers who will be directed to visit locations where Plan B® is available and purchase the product. Using the data collected, the sponsor will document and analyze the level of comprehension of the Plan B® prescription age requirement and how it is handled at the point of purchase. The program will be conducted twice in the first year and annually thereafter. The sponsor will report repeat violators to the relevant State Boards of Pharmacy.
- Report to FDA on the results of these activities on a six-month interval beginning 30 calendar days after the six-month interval commencing on the date of the approval of the amended sNDA.

Finally, I note and agree with the other elements of the CARE℠ program described in the submission of August 23, 2006, which are designed to help ensure compliance with the approved labeling, and particularly the restriction of OTC use to ages 18 and older. The program includes the following elements:

- The sponsor and third party distributors, wholesalers, and chain drug companies will only distribute Plan B® to licensed pharmacies or other licensed healthcare clinics. As a result, Plan B® will not be sold at gas stations or convenience stores. Given that Plan B® will have both Rx and OTC labeling, the pharmacies will keep Plan B® behind-the-counter.
- The sponsor will conduct an education campaign that will focus initially on healthcare professionals (including prescribers and pharmacists) to raise awareness and knowledge levels about emergency contraception. The education campaign will clearly communicate the prescription age requirement and the appropriate use of emergency contraception. The campaign will include continuing education by certified professionals and educational materials (including websites and toll free numbers) that can be accessed easily and at any time.
- The sponsor will make available to State Boards of Pharmacy continuing education programs for use at annual meetings and other regional programs.
- The sponsor will provide to prescribers and healthcare professional associations materials for distribution to patients that will encourage patients to discuss any questions about emergency contraception with a healthcare professional.
- The sponsor plans to educate consumers, in part by targeting consumers ages 18 to 44 to convey critical awareness and educational messages as well as

information about product availability, time sensitivity of use, and the age requirements to obtain Plan B® as a prescription or OTC product.

I conclude that the CARE℠ program is sufficiently rigorous to prevent young women from obtaining Plan B® over-the-counter without the supervision of a practitioner licensed by law to prescribe the drug. Monitoring of the program's effectiveness will allow FDA to assess whether further modifications will be necessary to prevent inappropriate use of Plan B®.

IV. Conclusion

In conclusion, I find that Barr's sNDA, as amended most recently on August 23, 2006, meets the statutory standards for approval as set forth in 21 U.S.C. 355(d).

CARE[SM] (CONVENIENT ACCESS, RESPONSIBLE EDUCATION) PROGRAM:

THE PROPOSED MARKETING, EDUCATION, DISTRIBUTION, MONITORING PROGRAM FOR PLAN B®

Introduction

The CARE[SM] (Convenient Access, Responsible Education) Program has been carefully constructed to help ensure that Plan B® will be used responsibly and appropriately. Plan B® is being proposed as an OTC product with a prescription-only requirement for women ages 17 years and younger. The sales and marketing plan has been designed to limit the availability of Plan B®, to the extent practical, to pharmacies and clinics, and to educate healthcare professionals and consumers within the target age groups regarding the availability and responsible use of Plan B®. The need to take Plan B® in as timely a manner as possible dictates that any responsible marketing program not only address healthcare professionals but also include extensive consumer education which includes a direct access component as a means of gaining such information. Thus, the CARE[SM] program contains elements that include an appropriate consumer education component. In addition, the sponsor will work closely with retail pharmacies and drug wholesalers to ensure that they will carry Plan B®, and that they will understand and follow the prescription age requirement for the dispensing of product to women age 17 years and younger.

Data suggests that there are several critical issues currently limiting access to Plan B®:

- The prescription requirement delays timely access to Plan B®;
- Pharmacies may not routinely stock Plan B®;
- Awareness of the availability of Plan B® is lacking among healthcare professionals as well as women of childbearing age, and

- Access to accurate sources of information about the product is limited.

The CARE[SM] program is intended to address these issues by providing sources of accurate and responsible information to both healthcare providers and consumers. It is also designed to provide a framework for pharmacies to ensure availability of Plan B® as an OTC product when sought by knowledgeable consumers who are 18 years and older. Women age 17 years and younger will require a prescription from their healthcare provider in order to obtain Plan B®. The CARE[SM] program is not intended to impact or change, who can lawfully prescribe or dispense Plan B® under prevailing state laws.

Four core elements of CARE[SM] contribute to the achievement of program objectives.

- Labeling/Packaging/Informational toll free number (to provide essential information to consumers in an accessible, easy to understand format. The proposed Plan B® packaging is designed to meet both prescription and OTC requirements.)
- Education (to provide information intended to educate physicians, pharmacists, pharmacy staff, nurse practitioners, and patients and to provide healthcare professionals with educational materials that they can supply to their patients to stimulate discussion. Educational initiatives will also focus on clearly instructing all audiences on the age requirement that will require women age 17 years and younger to obtain a prescription for Plan B®.)
- Distribution (to ensure, that Plan B® will be available only to licensed drug wholesalers, retail operations with pharmacy services and clinics with licensed healthcare practitioners, and to successfully facilitate the Plan B® prescription-only age requirement. These settings will also provide easy access by the consumer to a pharmacist or other healthcare professional should questions arise.)
- Monitoring (to evaluate the effectiveness of the program by determining if the age restriction is understood by all audiences and is properly being adhered to. Adjustments to the program will be made as appropriate.)

I. Labeling/Packaging

The proposed Plan B® labeling was developed to provide clear and comprehensive communication of the key messages outlined above, and to make known additional sources of information. The proposed Plan B® packaging is designed to meet all requirements of both a prescription and over-the-counter product and is consistent with that studied in the Plan B® Label Comprehension Study and the Plan B® Actual Use Study. In addition, minor changes to the packaging were made to reflect the comments from the FDA Joint Advisory Committee meeting of December 16, 2003. The proposed Plan B® packaging will allow pharmacies to appropriately dispense Plan B® as either a prescription or OTC product. The proposed package also provides educational information to the consumer in a patient friendly format.

Proposed elements of the package are as follows:

- The back of the package includes the Drug Facts as well as a space for the pharmacy to place the required prescription labeling;
- The statement, "Rx only for age 17 and younger" appears on the Principal Display Panel and "prescription only for age 17 and under" has been added to the Drug Facts panel of the package;
- The inner package houses the 2 Plan B® tablets and clearly states the steps for when to take Plan B®;
- The Plan B® Package Insert and an educational booklet designed for the consumer will be housed with the inner card;
- The toll-free number for the Plan B® 24-hour Information Line and the Plan B® web address are clearly displayed in the Drug Facts panel of the package should the consumer have additional questions on Plan B®.

II. Education

Given the very low levels of awareness of the availability of emergency contraception, the CARE[SM] Program provides for an intensively educational approach to the introduction of Plan B® as an OTC product for those age 18 years and older. The sponsor is proposing an educational program that will initially focus on healthcare professionals but will include limited direct-to-consumer advertising designed to stimulate discussions with healthcare providers. The program will assist healthcare providers in developing an adequate knowledge base so that they can provide responsible and accurate counseling to patients.

Efforts directed to raising consumer awareness of the product and its appropriate use will follow appropriate professional education programs. The educational materials will address not only Plan B® but will encourage healthcare professionals to urge users to adopt routine forms of contraception and avoid reliance on Plan B® as their primary form of birth control.

A. Educational Program to Healthcare Professionals.

Plan B® will be introduced and explained to healthcare professionals to raise awareness and knowledge levels as to emergency contraception. Education will also clearly communicate the prescription age requirement for Plan B®. Given the current lack of understanding of emergency contraception, this program is intended to ensure that healthcare professionals are prepared to support their patient populations.

1. Physicians, physician assistants, nurse practitioners, office staff, pharmacists and pharmacy staff are the primary audiences for this educational program. Pharmacists and pharmacy staff are especially important because they will need to be prepared to answer questions at the point of purchase and follow the protocol, when appropriate, for asking customers to provide government-issued identification of their age. Additional communication will be focused on pharmacists and their staff to ensure that they are knowledgeable of the prescription requirement for women age 17 years and younger, and that they understand how to appropriately dispense the Plan B® package in both prescription and OTC scenarios. Programs will include continuing education by certified professionals and educational materials (including websites and toll free numbers) that can be accessed easily and at any time. The sponsor will make available to the state boards of pharmacy continuing education programs for use at annual meetings and other regional programs. The sponsor will also encourage state boards of pharmacy to provide information to their members regarding the availability and appropriate use of Plan B®, as well as the prescription-only requirement for women age 17 years and younger. In addition, the sponsor will work closely with retail pharmacies to ensure that they have access to appropriate training materials for their pharmacists and pharmacy staff.

2. The sponsor's sales representatives[1] will communicate the prescription requirement for women age 17 years and younger, as well as the OTC availability of Plan B® for those 18 years of age and older. The sales representatives will also provide materials targeted for patients. Physicians, physician assistants and nurse practitioners will be asked to distribute the materials to patients. Materials will encourage patients to discuss any questions they have about emergency contraception or the specific use of Plan B® with

[1] The sponsor's sales force for female healthcare products, currently consisting of approximately 230 sales representatives, visit the offices of approximately 30,000 physicians, mostly Obstetricians and Gynecologists.

their physician or the nurse practitioner. Efforts to reach healthcare professionals to reinforce these messages will continue on an ongoing basis as part of the sponsor's professional communications program. The sponsor also will work with the relevant healthcare professional associations to provide educational programming and materials to reach those healthcare providers who will not be reached personally.

3. Key messages for consumers and healthcare providers will be tested through market research, including field-testing to ensure communication objectives are met.

B. Educational Campaign to Consumers

An information campaign to consumers will commence once the healthcare professional audience has been introduced to the product. This consumer education campaign is anticipated to begin about six months following product launch.

1. The campaign will be designed to convey critical awareness and educational messages as well as information about product availability, the time sensitivity of use, and the age requirements to obtain Plan B® as a prescription or OTC product. The intent will be to make consumers aware of the availability of emergency contraception, its appropriate use and the need to use it as soon as possible. Women age 17 years and younger will be encouraged to contact their healthcare professional to learn about emergency contraception, routine forms of birth control, and sexually transmitted infection (STI)/human immunodeficiency virus (HIV).

2. The direct to consumer campaign will be designed to target those ages 18 to 44.

   i) The language and visuals used will be appropriate and of interest to this targeted age group. New promotional materials will be provided for comment to FDA during the development process and will be tested via market research

to ensure appropriate communication according to current practices.

ii) Media placements that target audiences age 17 years and younger will not be used.

III. Distribution

The sponsor believes that in the interest of responsible usage (and in recognition of the circumstances of the need for emergency contraception), Plan B® should be available in those retail pharmacy outlets that typically sell a broad range of OTC medications and that have pharmacy services staffed with pharmacists (or, in the case of clinics, other healthcare professionals) during normal business hours to answer questions. Since Plan B® will have a prescription only requirement for women age 17 years and younger, Duramed Pharmaceuticals and the third party distributors, wholesaler distribution and chain drug companies, will only be allowed to distribute Plan B® to licensed pharmacies or other licensed healthcare clinics, as it would be unlawful to distribute a prescription product to any business that does not have a valid pharmacy license and/or physician license. Duramed has been in contact with at least three of the largest wholesaler distributors in the country as well as some of the largest retail chain drug accounts that purchase Plan B® directly from Duramed. Each of the wholesaler distributors and chain drug companies confirmed that, since Plan B® has both Rx and OTC labeling, they will treat Plan B® as any other Rx product for distribution purposes; specifically, that it would only be distributed to licensed pharmacies or healthcare clinics. Therefore, Plan B® will not be available at gas stations or convenience stores. Additionally, since Plan B® has both Rx and OTC labeling, the pharmacies will keep the product behind the counter and control it as an Rx product. The pharmacy and clinic settings will also allow pharmacists and other healthcare providers to properly restrict OTC access to those age 18 years and older.

IV. Monitoring

The sponsor intends to monitor trends in the use of emergency contraception to evaluate the effectiveness of the CARE[SM] program and will make adjustments as appropriate. Monitoring will be accomplished in several ways, with information gathered from both healthcare professionals and consumers.

Monitoring actual use of Plan B® is complex due to the difficulties inherent in identifying those who have purchased the product and in gathering useful, generalizable information. Consequently, the monitoring component will rely on a variety of sources intended to provide trend data, observational data, and signals of program effectiveness and potential problems. Monitoring components will include the following:

1. A market research survey or surveys of a subset of healthcare professionals (e.g. OB/GYN, family practice, pharmacists, nurses, family planning and health clinic personnel) annually, and when practicable, in collaboration with established professional groups e.g., National Association of Boards of Pharmacy (NABP), College of Obstetricians and Gynecologists (ACOG), American College Health Association (ACHA), National Association of Chain Drug Store (NACDS), Consumer Healthcare Products Association (CHPA), Healthcare Distribution Management Association (HDMA) to determine:

    - Whether the prescription requirement for women ages 17 and younger is understood and is being adhered to at the point of purchase
    - Attitudes toward and experience with patients' usage of Plan B®
    - Trends among emergency contraception users within their patient population (especially source of awareness, repeat use, use instead of more effective forms of contraception, incidence of STIs, etc.)

- Nature of interactions with Plan B® users (Does the contact with the healthcare professional occur prior to product usage? after usage? Are the women in search of contraceptive counseling? What types of side effects are being seen in use?)
- Areas where additional information is needed in the marketplace, as identified by the questions raised by the users

2. Using relevant survey data regularly collected by others (e.g. Centers for Disease Control's Behavioral Risk Factor Safety Surveillance (CDC BRFSS), Youth Risk Behavior Safety Surveillance (YRBSS), Foundations and Nongovernmental Organizations (NGO) surveys) the sponsor will monitor for potential indicators that Plan B® is being used in an inappropriate manner. Where existing surveys do not include relevant data, the sponsor may seek inclusion of appropriate questions. Potential areas of monitoring and reporting include:
   - Data and trends in STIs based on geographic areas;
   - Data and trends in pregnancy and/or abortion rates based on geographic areas;
   - The sponsor recognizes that the use of these sources may not give timely enough data to evaluate the CARE℠ program in the first few months of marketing. However, the commitment to monitoring extends beyond the initial stages of product introduction, and working with data sources to enhance collection of data relevant to use of Plan B® will be ongoing.
3. Gathering data from actual users of Plan B® is difficult because the number of users will be relatively small and because the decision to use emergency contraception is a private and emotional one. Women choosing to use the product are expected to wish to remain anonymous and are entitled to maintain their privacy. Nevertheless, the sponsor will work with a variety of sources in an effort to obtain and analyze consumer data in accordance with HIPAA

regulations to assess the effectiveness of the CARE[SM] program elements.

The sponsor proposes to provide FDA a monitoring report with the available results from the above monitoring activities on a six-month interval, with submission of the report within 30 calendar days after the six-month interval date, commencing on the date of the approval ofboth the Rx and OTC versions of Plan B®.

V. Monitoring Compliance with the Prescription Age Requirement

Monitoring compliance of the Plan B® Prescription age requirement can be somewhat complex because there will be no documented information on the purchasers of Plan B® who were old enough to obtain it as an OTC product. The Sponsor intends to monitor the level of comprehension of the Prescription age requirement particularly at the pharmacy level, where the age of consumers must be assessed at the point of purchase. The following program will provide accurate information directly related to accessing compliance:

- Point of Purchase Monitoring Program:

  The Sponsor will conduct a "Point-of-Purchase Monitoring Program", which intends to track how Plan B® is being sold at the time of purchase. Due to the challenges of obtaining specific purchase data on an OTC product and respecting consumer privacy, this program will include anonymous shoppers who will be directed to visit locations where Plan B® is available and purchase the product. These transactions will be documented and analyzed to determine the level of comprehension of the Plan B® prescription age requirement and how it is handled at the point of purchase. The shoppers in this program will be 15 to 18 years old. Parental consent will be obtained for shoppers under the age of 18 years. Locations for this program will be selected based on areas where Plan B® use is high, and will be in different regions of the US to provide a national representation of the findings. These findings would provide concrete

information on how the prescription age requirement for Plan B® is being addressed at the pharmacy and if it is properly being followed. The Sponsor will use these findings to identify areas where more education on the prescription age restriction is needed and will focus their efforts on improving the level of understanding among pharmacists and the pharmacy staff. Findings from the study will be communicated to the pharmacy, and the corporate office, if appropriate, since education and retraining will be the first course of remedial action. In the case of repeat violators, the violator's State Board of Pharmacy will be notified. Results of this point of purchase program will be provided to FDA as part of the 6-month report (see Section IV – Monitoring). The Point-of-Purchase Monitoring Program will be conducted twice in the first year (6 months after product launch and 12 months after product launch). This time period will allow the Sponsor to compare findings and identify areas where improvement was made and whether additional education is needed. The program will be conducted annually after the first year.